The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study title: Wearable Device for Prevention of Opioid-Induced Hypoxemia

Sponsor: NIH

Principal Investigator: Daniel Sessler, MD

Office hours phone contact #: 216-444-4900

After hours phone contact #: 216-870-2620

KEY INFORMATION

The following is a short summary of this research study to help you decide whether or not to be a part of this research study. More detailed information is included later on in this document.

What should I know about a research study?

- Someone will explain this research study to you.
- You can choose whether or not to take part.
- You can agree to take part and then later change your mind.
- Your decision whether or not to participate will not be held against you.
- You can ask all the questions you want before you decide.

What is the purpose, procedures and duration of this study?
We invite you to take part in a research study because you will have surgery and be given opioids (narcotics) to treat pain. Opioids treat pain well, but can interfere with breathing which can cause the amount of oxygen in your blood to decrease (low oxygen saturation). Low oxygen saturation means that less oxygen is delivered to organs which, in extreme cases, can damage them. The purpose of this study is to see if Oxalert can help detect low oxygen saturation and to alert you to breathe. The duration of the study will be less than 10 days.

More detailed information can be found under the section labeled: "Information on the Research."

Why might you choose not to participate in this research study?
You might not want to wear an investigational device. You may not like the way it fits, or be worried that the device will be uncomfortable.

More detailed information about the risks of this study can be found in the section labeled "Risks."

Why might you choose to volunteer for this study?
We cannot know if you will have any benefit as a result of your participation in the study. This study is being conducted to collect more information about a device that may benefit others in the future.

More detailed information about the benefits of this study can be found in the section labeled "Benefits."

What are my other choices if I do not take part in this study?
You do not need to be in this study. If you do not, you will have routine oxygen saturation monitoring and management.

DETAILED INFORMATION

The following is more detailed information about this study in addition to the information listed above.

1. INFORMATION ON THE RESEARCH

Why is the research study being done?
You are being asked to participate in this study because you will be given opioids (narcotics) to control pain after your surgery. Opioids treat pain well, but can interfere with breathing which can cause the amount of oxygen in your blood to decrease (low oxygen saturation). A novel device called the Oxalert measures how well you breathe and, if necessary, will tell you to breathe (a voice through a speaker) and, if necessary, generate a small electric shock. This study is being done to find out if the Oxalert prevents low oxygen saturation.

How Many People Will Take Part in this Study?
A total of 50 people will participate, all at the Cleveland Clinic Main Campus.

What is involved if you decide to take part in this research study?
If you agree to participate in this study, you will wear the Oxalert device for 24 hours sometime before surgery. We will then call you and ask you turn off the machine and send it back to us by pre-paid mail. When you come for surgery, you will also be randomized (like a flip of a coin) to one of the following groups:

> **Monitor without alerts:** After surgery and throughout your hospital stay, and for 24 hours after you go home, blood oxygen saturation will be recorded by the Oxalert, but no warnings of low saturation will be given.
>
> **Monitor and alerts:** After surgery and throughout your hospital stay, and for 24 hours after you go home, blood oxygen saturation will be recorded by the Oxalert. If necessary, the machine will remind you to breathe. If you do not breathe enough to make oxygen saturation normal within one minute, the machine will provide mild electric shocks to the wrist, with the strength of the shocks increasing over time. Both the voice and electric shocks will stop if you breathe enough to make oxygen saturation normal or if you press a button on the Oxalert device. Research is optional and you can remove the Oxalert device if it is uncomfortable.

On the second day after leaving the hospital, we will call you and ask a few questions about how much opioid you needed and how you feel about the Oxalert device. We will also remind you to turn off the machine and send it back by pre-paid post.

How will my data be used?
Your data may be sent outside of the Cleveland Clinic for analysis. Any personal information that could identify you will be removed before your data is shared.

Will I be notified of the results of the tests/studies on my samples?
The results from the device described are for research purposes only. It is not the purpose of these results to look for or provide you with any medical information or diagnoses relating to your present condition or any other disease or illness. Therefore, you will not receive results from these research tests/studies.

2. ALTERNATIVES
What are the alternatives to participation in the research study?
You do not need to be in this study. If you do not, you will have routine oxygen saturation monitoring and management. Whether or not you participate in the study, nurses will measure your oxygen saturation as necessary, usually every 4 hours.

3. RISKS
What are the risks of participating in the research study?
All routine clinical monitoring and care will be provided. You will never get less-then-routine care by being in this study. The Oxalert is an experimental device that has not been cleared by the Food and Drug Administration (FDA). The battery-powered device is worn on the wrist (like a big watch) and connected to two pads on the back of the hand and to one finger. Wearing the device may be uncomfortable. The audible alerts will only happen if you are not breathing enough; the electric shocks to the wrist will only happen if you are not breathing enough *and* do not respond to the voice telling you to breathe. Both will stop if you start breathing well or if you press the "stop" button. If you press the "stop" button, monitoring by the Oxalert will stop, but routine monitoring by nurses will continue. The audible voice and electric shocks may be annoying, but they are not dangerous.

We will record information about your medical history, hospital stay, and study results. Some of these data may be shared with the Oxalert company, but we will not give the company your name or identifying information. Your data will be kept confidential, but there is a potential risk of loss of confidentiality.

Confidentiality Risks
There is a potential risk of loss of confidentiality of your data. Every effort will be made to keep your information confidential through the use of the following safeguards: If you decide to be in this study, the study researchers will get information that identifies you and your personal health information. This may include information that might directly identify you such as your name and address. This information will be kept for the length of the study. The principal investigator will keep a link that identifies you to your coded information, but this link will be kept secure

and available only to the principal investigator and select members of the research team. Any information that can identify you will remain confidential. Any personal information that could identify you will be removed or changed before files are shared with other researchers or results are made public.

Unknown Risks

There may be risks or side effects related to the study device that are unknown at this time. You will be notified of any significant new findings that become known that may affect your willingness to continue in the study.

4. BENEFITS

What are possible benefits of participating in the research?

If you participate in the study and are assigned to alert group, the voice and electric shocks might decrease the amount of time during which you have low oxygen saturation. Knowledge gained from this research may help others.

5. COSTS

Are there any costs to you if you participate in this study?

You will not be charged for taking part in this study. The study equipment, follow up, mail back the equipment and other procedures associated with the study will be at no cost to you.

6. PAYMENT

Are there any payments to you if you participate in this study?

We will pay you $3/hour of device use during the pre-hospital and post-hospital days, and $3/hour in the hospital for up to 5 days. Payment will be made by check, about 2 months after the device is mailed back to us.

7. RESEARCH RELATED INJURY

What will happen if you are injured as a result of taking part in the research?

In the event you suffer a research related injury as a result of being in this study, Cleveland Clinic will provide appropriate medical treatment for such injury in a timely manner. Provision of such medical treatment does not imply any negligence or other wrongdoing on the part of Cleveland Clinic or any of the physicians or other personnel involved in the study. If you believe that you have been injured as a result of participating in the study, please immediately contact your Cleveland Clinic study doctor even if you may have already been seen or treated by another doctor. If you are seen or treated by a doctor other than the study doctor, you should inform such doctor that you are in this study and, if possible, take this document with you as it may help such doctor treat you.

In the event you suffer a research related injury as a result of being in this study, the costs for medical treatment may be billed to you or your medical insurance plan, if applicable. Medical insurance plans may or may not cover costs for medical treatment of research-related injuries. If you have insurance, you should check with your medical insurance plan before deciding to participate in this research study. In the event your medical insurance plan covers some or all of the treatment costs, you may still be responsible for co-pays or deductibles as required by your medical insurance plan.

Cleveland Clinic has not set aside any money to pay you or to pay for your treatment if you suffer a research related injury as a result of being in the study. There are no plans for Cleveland Clinic to provide other forms of compensation (such as lost wages, pain and suffering, or other direct or indirect losses) to you for research related injuries. You are not waiving any legal rights by signing this form, including the right to seek compensation for an injury. Further information about research related injury is available by contacting the Institutional Review Board at (216) 444-2924.

8. PRIVACY AND CONFIDENTIALITY

What will happen to your information that is collected for this research?

Cleveland Clinic may share your study information, without anyone knowing that it is related to you specifically, with others or use it to research projects not listed in this form. Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them.

Study results may be shared in medical journals, at scientific meetings, and in other media without your identifying information. Your records will be confidential and your identity will not be shared in medical journals, at scientific meetings, and in other media without your express consent.

We would like to keep your information to use in future research related to this project about outcomes from Oxalert. Consenting to this is optional. You can still participate in the main study without participating in this optional section to use your information in future research related to outcomes from Oxalert.

Initial here: _____Yes _____No

Authorization to Use/Disclose Protected Health Information

Cleveland Clinic has rules and procedures to protect information about you. Federal and State laws also protect your privacy.

The research team working on the study will collect information about you. This includes your health information, data collected for this research study and personal identifying information including your name, address, date of birth, Social Security number, and other identifying information.

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Cleveland Clinic may see or give out your information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff.

People outside Cleveland Clinic may see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals

in the study and the sponsor of the research and their agents. Cleveland Clinic will take steps to ensure your information is kept confidential and that only the health information which is minimally required to conduct the study is used or disclosed to people outside Cleveland Clinic; however, people outside Cleveland Clinic who receive your information may not be covered by this promise.

You do not have to give this permission to use and give out your information; however you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.

You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing, Daniel Sessler, MD 9500 Euclid Avenue, Cleveland, OH 44195. If you do cancel your permission to use and disclose your information, your participation in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

Certificate of Confidentiality

This added protection to your privacy, limits the re-disclosure of your private identifiable data by the researchers without your permission in any federal, state, or administrative proceedings.

The Certificate will not prevent the researchers from notifying the appropriate authorities when there is a federal, state or local law that requires reporting, such as reporting communicable diseases or child/elderly abuse. The Certificate cannot be used during required auditing or evaluation of federally-funded projects or when required by the Federal Food and Drug Administration (FDA).

This Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer or employer learns about your participation, and obtains your consent to receive research information, we may not use the Certificate of Confidentiality to withhold this information. This means you must actively protect your own privacy.

If you have any questions about what this notice means and would like to speak to someone, you may call the study's Principal Investigator, Daniel Sessler, MD at 216-444-4900, or the Institutional Review Board (216-444-2924). If you would like to read more about Certificate of Confidentiality, the NIH has a website you can visit online at: https://grants.nih.gov/policy/humansubjects/coc.htm.

Clinical Trials Language

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

9. QUESTIONS

Who do you call if you have any questions or problems?

If you have any questions or concerns about the research, or develop a research-related problem, you should contact **Daniel Sessler, M.D. at 216 444-4900.** During non-business hours, weekends and holidays, please contact **Kai Li, MD at 216-444-8476 or pager 216-444-4000 X81823**. If you have questions about your rights as a research subject, you should contact the Institutional Review Board at (216) 444-2924.

10. VOLUNTARY PARTICIPATION

What are your rights as a research participant?

Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your study doctor your decision to ensure a safe withdrawal.

If you leave the study early, Cleveland Clinic may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

11. SIGNATURES

Statement of Participant

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____
Printed name of Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date