

A PROOF OF CONCEPT, RANDOMIZED, SINGLE CENTER, STUDY ON
FRAMEWORKS FOR WEARABLE DEVICES TO SENSE AND
RESPOND TO OPIOID OVERDOSES

NCT # 834304
01/14/2020

**A UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND
HIPAA AUTHORIZATION FORM**

Protocol Title: A PROOF OF CONCEPT, RANDOMIZED, SINGLE CENTER, STUDY ON FRAMEWORKS FOR WEARABLE DEVICES TO SENSE AND RESPOND TO OPIOID OVERDOSES



Why am I being asked to volunteer?

You are being invited to participate in a research study. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form. 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.

What is the purpose of this research study?

The purpose of this study is to learn about opioid users' needs and preferences in order to develop a medical device to help those that suffer an overdose. If you agree to join the study, you will be asked to complete a questionnaire and could be shown potential device designs with the purpose of asking your opinion on design and comfort. The DOVE (Delivery of Opioid agonists for Ventilatory Emergencies) device is a wearable device that has components that may noninvasively sense opioid overdose and

administer commercially available opioid antagonist. The DOVE device prototype is investigational. It has not been approved or cleared by the FDA.

How long will I be in the study?

The length of your participation will be approximately three months. There could be a second visit in which different device prototypes are shown to you with the goal of obtaining your opinion and feedback of the different DOVE device prototype design. Both visits could take place on the same day. The length of the visit will be approximately 30 minutes.

What am I being asked to do?

If you take part in this study, you will be asked to complete a questionnaire. There could be a second visit in which we ask your feedback on different device prototypes regarding how they look and how comfortable they are. Both visits could take place on the same day.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

If you agree to take part in this study, there will be no direct medical benefit to you. We cannot promise that you will experience medical benefits from participating in this study. We hope the information learned from this study will benefit others in the future.

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

Because being in this study is completely voluntary, the other option is not to be in the study.

Will I be paid for being in this study?

Subjects will be paid for participating in this study. You will receive \$10 once you complete the questionnaire and \$5 for going over the different device prototypes. Payment will be provided in the form of gift cards.

Will I have to pay for anything?

There are no costs to you for being in the study and you have no financial obligations to this study. You or your insurance company will not have to pay for your research participation.

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

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by your physician or the principal investigator, without your consent because:

- The principal 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.
- The principal investigator has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future medical or pain care.

Who can see or use my information? How will my personal information be protected?

There is a risk of breach of confidentiality (unintentional release of your information). 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. We will protect your confidentiality during storage and sharing by keeping all data 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. 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. 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. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records.

What is an Electronic Medical Record and/or a Clinical Trial Management System?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any information produced from your participation in this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR or in the CTMS, your information may be accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc.).

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

- Name, address, telephone number, date of birth
- Medical history

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.

Who may use and share information about me?

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. Confidentiality may be breached if you disclose any intent to harm yourself or others, or disclose elder or child abuse.

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, 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 the School of Medicine, might receive my information?

- All research centers participating in the study.
- The funding sponsor and organizations supporting the sponsor.
- 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 University of Pennsylvania procedures developed to protect your privacy.

Oversight organizations

- The U. S. Office of Human Research Protections (OHRP)

Once your personal health information is disclosed to others outside the School of 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 University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?

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

Your information may be held in a research database. However, the School of 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 the School of 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 Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (---) - - - - -.

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