HUMAN RESEARCH
CONSENT FORM

Attitudes, Beliefs and Barriers to Adopting an Automated Naloxone Delivery System to Overcome Opioid Overdose – Interviews of Opioid Injectors and Physicians

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

The Institutional Review Board at California Pacific Medical Center wishes you to know: Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of both the procedures to be followed in the medical experiment, as well as any drug to be used in the experiment.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment.
5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of the signed and dated written consent form when one is required.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

You are currently set to receive text messages for appointment reminders and information about your health care treatment, but you will not receive text messages about promotions or other services. If you wish to change your preferences receiving all text messages from CliniOps, you can login to the portal and update your preferences.

If you have questions regarding a research study, the researcher or his/her assistant will be glad to answer them. You may seek information from the Institutional Review Board--established for the protection of volunteers in research projects--by calling (415) 600-3688 Monday through Friday, between 9:00 a.m. and 4:00 p.m.

_____ _____

Participant's Signature Date

MEDICAL RECORDS: ***DO NOT DELETE THIS SIGNED FORM FROM PATIENT'S CHART***

CALIFORNIA PACIFIC MEDICAL CENTER
CONSENT TO ACT AS A RESEARCH PARTICIPANT

The Principal Investigator is John Mendelson, MD.

This study was explained to you by: Dr. John Mendelson.

A. WHAT IS THE PURPOSE OF THIS STUDY?

You are being asked to participate in a research study at California Pacific Medical Center's Addiction and Pharmacology Research Laboratory (APRL) because you are on the CPMC or St Luke's Medical Staffs and administer opiates during medical procedures. Over the last 10 years opiate overdose has increased dramatically and now exceeds automobile accidents as a cause of death in young people. Perhaps surprisingly the increase in deaths is mostly due to overdoses of prescription opiates. The investigators are developing a machine that can detect a heroin overdose and automatically administer naloxone. Although patients having their opiates titrated and heroin users are the most likely end users the developers are interested in the opinions of another group of likely users of this machine– physicians who administer opiates in non-intubated patients during medical procedures. You are being asked to participate because you administer opiates in clinical settings.

The study will take place at either in your offices or at the **Addiction and Pharmacology Research Laboratory** located at St. Luke's Hospital, 3555 Cesar Chavez Street, San Francisco, CA 94110.

B. HOW MANY PEOPLE WILL PARTICIPATE?

A total of 18 people will take part in this study; 9 will be physicians and 9 will be heroin injectors.

C. HOW LONG WILL I BE IN THIS STUDY?

The entire study, including screening, will take no more than two hours. If you agree to take part in this study, you will first complete a short screening process so that we can determine if you meet the requirements for this study. The screening process may take up to 15 minutes. You will not be paid for the screening time. After screening you will participate in a 1-1½ hour interview. The interview is the only study procedure.

D. WHAT WILL HAPPEN TO ME DURING THIS STUDY?

Screening Visits

During the screening process, you will first review this consent form with one of our researchers, and, if interested in participating, sign this consent form. The entire screening process for this study may take 15 minutes.

Once You are in the Study

If the screening procedures show that you are eligible, and you choose to continue, you will be scheduled for the interview. The interview will be conducted by Dr Mendelson with the assistance of one of the research staff. Most of the interview will be videotaped. The tapes will be used to transcribe specific comments and review the notes taken during the interview. They will only be seen by the members of the CPMC research team and they will be erased as soon as the information is reviewed by the team. The interview will start with a description of your experience and practice. You will then be handed a model of the overdose detection and treatment system. You will be encouraged to manipulate the model and attach the various sensors that are needed to detect overdose. The sensors that help detect overdose need to be placed on the arm, the fingers and the neck. We are interested in how acceptable and practical hooking up these sensors are. Thus, will have you rate all of the components and tell us if you would use the device. After the rating is done the study is over.

E. WHAT ARE THE RISKS OF THIS STUDY?

There are no risks of participating.

F. WHAT ARE THE POTENTIAL BENEFITS TO ME AND OTHERS?

There will be no direct benefit to you from participation in this study. However, it is hoped that the information gained from the study will ultimately help in preventing deaths from opiate overdose.

G. WHAT OTHER ALTERNATIVES OR TREATMENT OPTIONS ARE AVAILABLE TO ME?

This is not a treatment study. You are free to choose not to participate in this study.

I. HOW CONFIDENTIAL ARE MY RECORDS?

Participation in research may cause a loss of privacy. We will keep your participation in this research study confidential to the extent permitted by law. You will be assigned a code number for this study and all documents pertaining to you will be labeled with this code number, rather than your name. Subject identifiers will not be released to the sponsoring organization (Creare Inc./NIDA) under any circumstances.

Portions of your interview will be videotaped. The only people who will see the tapes work directly for Dr Mendelson. Videotapes will be erased as soon as the research team completes a review of your interview but in no case will tapes be kept for more than six months. The tapes will not contain your name. Only illustrative comments will be transcribed; complete transcriptions will not be done. The investigators will use the tapes to evaluate your interactions with the device model and to assure your salient comments are faithfully captured. Transcribed comments will be kept until the project is completed – potentially for many years.

J. IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all.

What if I Decide to Drop Out of the Study?

You are free to withdraw your consent to participate further at any time. The researchers may ask you to discuss your concerns with them to find a mutually-agreeable solution before you decide to leave. There will be no penalty of any sort should you decide to withdraw.

Can Someone Else End My Participation in this Study?

Under certain circumstances, the researchers may decide to end your participation in the study earlier than planned. This might happen if you fail to follow the rules of the study, and the researchers reserve the right to terminate you from further participation in this study if participation may be contributing to the development of medical or psychological problems.

K. WILL I BE PAID FOR PARTICIPATING?

If you complete the interview, you will receive a $100.00 gift card for your participation.

Payments will be made by gift card at the conclusion of your interview. Payments for participating in research are considered tax reportable income. The CPMC Research Institute will report to the IRS income in excess of $600 per year for research participation. You must provide a home address and social security number to receive payments for participating in this study. The reason or purpose of the payment will not be reported to the government.

L. WHO IS FUNDING THIS STUDY?

The National Institutes on Drug Abuse (NIDA), a division of National Institutes of Health (NIH), is funding the conduct of this study through Creare Inc., an engineering research & development firm. This means that California Pacific Medical Center is receiving payments from NIDA, through Creare Inc., to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or an increase in salary from NIDA or Creare for conducting this study.

California Pacific Medical Center has a financial conflict of interest policy, we provide education to our researchers on transparency in research and we have a management plan for identifying and mitigating financial conflicts of interest. You should feel free to ask your physician or access the CPMCRI website http://www.cpmc.org/professionals/research/irb/conflict.html for any concerns you may have.

M. WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study, other than the costs of getting to and from the research facility.

N. WILL I RECEIVE NEW INFORMATION ABOUT THE STUDY WHILE PARTICIPATING?

During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation that might cause you to change your mind about continuing in the study. If new information is provided to you about the risks or benefits of this study, your consent to continue participating in this study will be re-obtained.

O. EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

A copy of the Experimental Subject's Bill of Rights and a copy of this consent form will be given to you for your own use.

P. WHAT IF I HAVE QUESTIONS?

We encourage you to ask us any questions now. If you have any questions about the research study at any point, you may contact the study coordinator at (415) 641-3370.

Should you have any questions about your rights as a research participant, you may call the Institutional Review Board, which is concerned with protection of volunteers in research projects, between 9 a.m. and 4 p.m., Monday through Friday, at (415) 600-3688 or by writing: California Pacific

Medical Center Research Institute (CPMCRI) Institutional Review Board Office, 2200 Webster Street, #514, San Francisco, CA, 94115.

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SIGNATURE OF RESEARCH SUBJECT OR LEGAL REPRESENTATIVE

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this consent form, the Subject's Experimental Bill of Rights, and a copy of the Authorization for the Use and Disclosure of Protected Health Information for Research form.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

Participant's Signature	**Signature of Person Conducting Consent Discussion**
Date	**Date**

MEDICAL RECORDS: ***DO NOT DELETE THIS SIGNED FORM FROM PATIENT'S CHART***