Study name: Use of Virtual Reality for Overdose Management Educational Trainings

Short title: VR OD Education

Registration: NCT04091659

Attached protocol approved by University of Pennsylvania Institutional Review Board:

08/22/2019 10:07:46 AM

**Informed Consent Form**

**Title of the Research Study:** Examining the Use of Virtual Reality for Overdose Management Educational Trainings

**Protocol Number: N/A**

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You are being asked to take part in a research study. Your participation is voluntary which means you can choose whether on not to participate. If you decide to participate or not to participate there will be no loss of benefits to which you are otherwise entitled. Before you make a decision, you will need to know the purpose of the study, the possible risks and benefits of being in the study, and what you will have to do if you decide to participate. The research team is going to talk with you about the study and give you this consent document to read.

If you do not understand what you are reading, do not sign it. Please ask the researcher to explain anything you do not understand, including any language contained in this form. If you decide to participate, you will be asked to sign this form and a copy will be given to you. Keep this form, in it you will find contact information and answers to questions about the study. You may ask to have this form read to you.

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## What is the purpose of the study?

The purpose of the study is to evaluate the efficacy of two different educational training approaches to teaching opioid overdose intervention management: online video/printed materials and a virtual reality training.

**Why was I asked to participate in the study?**

You are being asked to join this study because you are a local community member attending the Department of Public Health's naloxone trainings at the library.

**How long will I be in the study? How many other people will be in the study?**

If you agree to take part in this study, you may be asked to participate in a 9-minute virtual reality simulation and complete two electronic surveys: one before the simulation, and one immediately after. The surveys will take approximately 10 mins each to complete.

Alternatively, you may be asked to take part in this study by permitting the research team to access your responses before and after viewing printed materials or online videos about how to administer naloxone.

We anticipate approximately 100 members of local Philadelphia communities to participate in this study.

**Where will the study take place?**

If you decide to take part in the study, it will take place at your local library at a table in the lobby or in a public conference room within the library.

**What will I be asked to do?**

- If you agree to take part in this study, you may be at a library randomized to the virtual reality group or to the online video/printed handout group.
- If you are assigned to the virtual reality group, you will be asked to participate in a 9-minute virtual reality simulation.
- Regardless of training group you will be asked to complete two surveys, electronically. One survey will be completed before the virtual reality simulation and the other will be completed immediately after.
- If you do not feel comfortable or would not like to participate in the virtual reality group, you may choose to only consent to participate in the online video group.

**What are the risks?**

The risks for participants in this study are minimal; the study questions are non-invasive, and the experimental virtual reality simulation is safe and widely accepted as an educational technique. If at any time you feel uncomfortable during the virtual reality simulation, you are under no obligation to complete it or you may take breaks as needed. Your participation is voluntary. The information that you provide in the surveys will remain confidential and no identifying information will be asked from you. All study records will be maintained in a locked room dedicated to research at the School of Nursing and all electronic data will be stored on a secure firewall protected server.

**How will I benefit from the study?**

There is minimal benefit to you. We anticipate that after either training you will be more informed on how to respond during an opioid related overdose. Your participation could help us understand how others can retain knowledge and attitudes about responding to opioid overdoses through these two educational techniques. In the future, this may help other people who are seeking to learn how to intervene in an opioid overdose gain knowledge and confidence.

**What other choices do I have?**

Your alternative to being in the study is to receive public health department printed materials or watch video but not complete any surveys.

**What happens if I do not choose to join the research study?**

You may choose to join the study, or you may choose not to join the study. Your participation is voluntary.

There is no penalty if you choose not to join the research study. You will lose no benefits or advantages that are now coming to you or would come to you in the future. Your library staff will not be upset with your decision.

- There are no negative consequences should you choose not to participate in this study.

**When is the study over? Can I leave the study before it ends?**

The study is expected to end after all the Department of Public Health's trainings have been completed The study may be stopped without your consent for the following reasons:

  - The PI feels it is best for your safety and/or health - you will be informed of the reasons why.
  - You have not followed the study instructions

- The PI, the sponsor or the Office of Regulatory Affairs at the University of Pennsylvania can stop the study anytime

You have the right to drop out of the research study at anytime during your participation. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so. Withdrawal will not interfere with your future employment.

If you no longer wish to be in the research study, please contact Nicholas Giordano at **ngio@upenn.edu**

**How will confidentiality be maintained and my privacy be protected?**

The research team will make every effort to keep all the information you provide us during the study strictly confidential, as required by law. The Institutional Review Board (IRB) at the University of Pennsylvania is responsible for protecting the rights and welfare of research volunteers like you. The IRB has access to study information. We plan to publish the results of this study but will not include any information that would identify you. We will not be collecting your name, contact information, and any identifying information.

To keep your information safe, all hard copy information will be placed in a locked file cabinet at the School of Nursing. All electronic data will be securely stored on a computer that is password-protected and uses special coding of the data to protect the information.

Under federal privacy regulations, you have the right to determine who has access to your personal health information (called “PHI”) which provides safeguards for privacy, security and authorized access. No PHI will be collected for this research.

**What happens if I am injured from being in the study?**

If you are injured and/or feel upset and emotional discomfort while participating in the study you may contact the PI or the emergency contact name on the first page of this form. Also, you may contact your own doctor, counselor or seek treatment outside of the University of Pennsylvania. Bring this document, and tell your doctor/counselor or his/her staff that you are in a research study being conducted at the University of Pennsylvania. Ask them to call the numbers on the first page of this form for information.

If you are injured and/or feel emotional discomfort from being in the study, the appropriate care will be provided without cost to you, but financial compensation is not otherwise available from the University of Pennsylvania. If you are injured and/or feel emotional discomfort while in the study but it is <u>not related</u> to the

study, you and your insurance company will be responsible for the costs of that care.

**Will I have to pay for anything?**

- There are no costs associated with participating in this study.

**Will I be compensated for participating in the study?**

- No.

**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 (215) 898-2614.

When you sign this document, you are agreeing to take part in this research study. If you have any questions or there is something you do not understand, please ask. You will receive a copy of this consent document.

Do you have any questions? Do you agree to participate in this study?

☐ **Yes:** I agree to participate in this study by permitting the research team to access my survey data and by agreeing to participate in a virtual reality simulation, if I am asked.

☐ **Yes:** I agree to participate in this study only by permitting the research team to access my survey data.

☐ **No:** Thank you for your time.

Signature of Subject

Print Name of Subject

Date

Signature of Person Obtaining Consent

Log out

# Submission Activity

Back to submission list | View as Pdf | Printer friendly

| | |
|---|---|
| **Confirmation number:** | cjgbgeif |
| **IRB status:** | Exempted |
| **Created by:** | GIORDANO, NICHOLAS A |
| **Principal investigator:** | GIORDANO, NICHOLAS A |
| **Protocol title:** | VR OD Education |
| **Protocol description:** | This cluster-randomized trial will compare changes in attitudes and knowledge on administering naloxone based on exposure to either a virtual reality educational training or the current standard educational trainings (e.g. on-line videos, printed information handouts) offered at local libraries. Individuals attending local library's naloxone training days will voluntarily complete an anonymous validated survey pre and post attending either the virtual reality or standard educational training. |
| **Resubmission:** | No |
| **Application type:** | EXEMPT Category 1 |

**View Protocol Application Form**

## List of Attached Documents

There are no documents.

**Revision History:** **Assigned to IRB #8, created on 08/08/2019 (cjgbgeif)**

## Department Review History

| Date | Reviewer | Dept Approval | Comments |
|---|---|---|---|
| 08/11/2019 06:13:27 PM | GIORDANO, NICHOLAS A | Approved | Principal Investigator submitted the protocol. |
| 08/12/2019 05:37:40 AM | COMPHER, CHARLENE W | Approved | |

## IRB Review History

| Decision date | Reviewer/approver | Decision |
|---|---|---|
| 08/22/2019 10:07:46 AM | IRB chair/designee | Approved |

## IRB Correspondence

| Date | Attached by | Attachment |
|---|---|---|
| 08/23/2019 | BURGESS, BARBARA K | **EXEMPTED (2019-8-22exemptgiordano833978kb.pdf)** |

## Ancillary Committee Correspondence

*None*