Protocol Information

Attached to Protocol: IRB-AAAS5667
Principal Investigator: Rachel Shelton (rs3108)
IRB Protocol Title: Investigating the Dissemination and Implementation of Opioid Education and Naloxone Training on College Campuses

General Information

Consent Number: CF-AABS4800
Participation Duration: 12 months
Anticipated Number of Subjects: 400
Research Purpose: Research is needed to determine the acceptability, feasibility, adoption, and implementation of opioid awareness education and naloxone training programs on college campuses. Informed by innovative methods and frameworks from implementation science, the proposed research will be used to inform development of a future R01 application focused on understanding factors that impact and strategies to support the broader dissemination and implementation of such training and educational programs among colleges and universities nationally.

Contacts

<table>
<thead>
<tr>
<th>Contact</th>
<th>Title</th>
<th>Contact Information</th>
</tr>
</thead>
</table>
| Rachel Shelton | Principal Investigator | Phone: 617-699-6557  
|                |                     | Email: rs3108@cumc.columbia.edu |
| Michael McNeil | Investigator        | Phone: 212-854-1662 |

Information on Research

Introduction
The purpose of this form is to give you information to help you decide if you want to take part in a research study, including information about:

- why the study is being done;
- the things that you will be asked to do if you are in the study;
- any known risks involved;
- any potential benefit;
- options, other than taking part in this study, that you have.

The Principal Investigator (the lead researcher for this project) or one of the Co-Investigators will discuss the study with you. If at any time you have questions about the study, please ask a member of the study team. Take all the time you need to decide whether you want to take part in this research study.

**About the Study**
As part of this study, you will be asked to participate in a training and educational session tailored to the needs, knowledge and attitudes of undergraduate students. Prior to the training, you will complete a short survey about your views and background regarding opioid overdose prevention, experience with and attitudes towards the administration of naloxone, and comfort level and willingness to engage in various activities related to overdose prevention. The training will focus on the benefits and importance of naloxone in relation to opioid use/misuse/overdose as well as the application of naloxone kits. After the training, you will be asked to complete a short-term and a long-term follow-up survey. There will be about 800 participants in the training group. The training will take approximately 1 hour and will take place on the Morningside campus.

**Risks**
The potential risk is minimal. There may be some personal discomfort with the topics of the training related to opioid use and naloxone, and awareness of opioid risks. Participants with questions or concerns regarding the content discussed will be encouraged to contact Columbia Health.

**Benefits**
Participants may not receive direct benefits from participating in this study. Pilot the naloxone training and education campaign among priority student populations, faculty and administration; and gathered important data on the feasibility, acceptability, appropriateness, and adoption of the proposed intervention, including important barriers and facilitators to adoption and implementation and the short-term impact of the training.

**Alternate Procedures**
As this is a research study conducting a purposeful sampling, no alternatives to the study are available. Subjects may choose not to participate in the study.

Confidentiality

Confidentiality
Any information collected during this study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised. Despite all of our efforts, unanticipated problems, such as a stolen computer may occur, although it is highly unlikely.

Your comments and participation will be separated from your name or any other information that could identify you. All data will be maintained on a Columbia University secured drive and only study personnel will have access.

The following individuals and/or agencies will be able to look at and copy your research records:
- The investigators, study staff and other professionals who may be evaluating the study
- Authorities from Columbia University, including the Institutional Review Board ('IRB')
- The Office of Human Research Protections ('OHRP').

Compensation

Compensation
Participants in the training group will receive a $20 gift card in appreciation for participating and will be able to complete a no-cost Naloxone training. Upon completion of the Naloxone training, participants will be asked to fill out the Narcan/Naloxone Recipient Form (NRF). The naloxone kit recipient completes the top half of the NRF and prints their name on pre-filled blue Certificate of Completion card. Naloxone kit recipient gives the NRF and the completed blue Certificate of Completion card to trainer and the trainer will put the blue Certificate of Completion card inside of naloxone kit and hands the kit to the trained recipient.

Voluntary Participation

Voluntary Participation
Participation in this study is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.
Who can I call if I have questions?
You may call Dr. Michael McNeil at 212-854-1662 if you have any questions or concerns about this research study.

If you have any questions about your rights as a research subject, you should contact the Human Research Protection Office and Institutional Review Board by phone at (212) 851-7040 or by email at askirb@columbia.edu.

More information about taking part in a research study can be found on the IRB website at http://www.columbia.edu/cu/irb

Statement of Consent

PARTICIPANT’S STATEMENT

I have read the above purpose of the study, and understand my role in taking part in the research. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later, about the research, I can ask the investigator listed above. I understand that I may refuse to participate or withdraw from participation at any time without jeopardizing my employment, student status or other rights to which I am entitled. The investigator may withdraw me at his/her professional discretion. If I have questions about my rights as a research participant, I can call the Institutional Review Board office at (212) 851-7040. I certify that I am 18 years of age or older and freely give my consent to participate in this study. I will receive a copy of this document for my records.