INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

Developing and Testing the Opioid Rapid Response System
National Institutes of Health (NIH); Project# 1R41DA053078-01

ABOUT THIS RESEARCH
You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

TAKING PART IN THIS STUDY IS VOLUNTARY
You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with Indiana University.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to develop and test the effectiveness of an Opioid Rapid Response System for reducing deaths from opioid overdoses. Opioid overdose events require a rapid response, which is often not available through standard emergency procedures. This study aims to develop a system for recruiting, training, and linking citizen responders to these events so they can administer lifesaving Naloxone/Narcan.

You were selected as a possible participant because you indicated that you are willing to take Naloxone/Narcan training, aged 18 or over, living in Boone, Hancock, Monroe, Dearborn, or Madison Counties of Indiana, and able to understand and complete questionnaires and training procedures in English.

The study is being conducted by Dr. Michael Hecht of REAL Prevention LLC, Clifton, New Jersey, and Mx. Cris Henderson and Dr. Wasantha Jayawardene of Prevention Insights, Indiana University School of Public Health-Bloomington. It is funded by the National Institute on Drug Abuse.

HOW MANY PEOPLE WILL TAKE PART?
If you agree to participate, you will be one of 400 participants taking part in this study.

WHAT WILL HAPPEN DURING THE STUDY?
If you agree to be in the study, you will do the following things.

- Participation in this study will require two types of activities:

    - Filling out questionnaires
    - Complete Naloxone/Narcan training
- At the beginning and end of the study, we will ask for some information to know about your basic demographics, such as age, gender, and zip code, your attitudes, knowledge, and any training in relation to opioid overdoses, your expectations from this training, your satisfaction about this training, and how you are going to use this training to help your community. You can fill out all these questionnaires online.
- The Naloxone/Narcan training will be online, and we will provide the necessary instructions.
- At the beginning and end of the study, it may take up to 20 minutes to fill out the questionnaires. The online Naloxone/Narcan training will last up to one hour.
- The training will consist of powerpoint slide shows, videos, and other interactive learning methods. Naloxone/Narcan training kits will be shipped to you.
- Filling out the questionnaires at the beginning and end of the study are for experimental purposes, and we expect you to complete all of these activities. If you do not choose to participate in the study, you do not have to complete any of these activities.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

While participating in the study, the risks, side effects, and/or discomforts include:
There will be no immediate physical, psychological, social, legal and economic risks or discomforts associated with this study. There is a small chance that you will feel uncomfortable responding to some questions in assessment questionnaires, but you do not have to disclose anything you feel uncomfortable sharing in the group. Similarly, there is a small chance that you will feel uncomfortable watching some videos and performing some activities during Naloxone/Narcan training. During the online training, you can inform this to the trainer either by online-chat, email, or phone. The trainer will provide you with advice to help you overcome the discomfort or obtain medical assistance if necessary. To minimize the risk of discomfort, however, we have tested and adjusted the questionnaire items and training procedures repeatedly prior to this study. There are no other expected risks to you for participating in this study.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?

The benefits to participation in the study that are reasonable to expect are skills and satisfaction. You will gain skills in responding to opioid overdoses. You may also gain the satisfaction of contributing to the health and well-being of your community and potentially save lives.

HOW WILL MY INFORMATION BE PROTECTED?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study.

A description of this clinical trial will be available on **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 this website at any time.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, National Institutes of Health (NIH), and state or federal agencies who may need to access the research records (as allowed by law).

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information or documents that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information or documents protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
(4) for the purpose of auditing or program evaluation by the government or funding agency.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

As there is a possibility that we invite you to participate in a future study related to this study, we will retain your contact details for three years for the purpose of re-identification. Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Information collected from you for this study may be shared with other researchers for future research. If this happens, information which could identify you will be removed before any information are shared. Since identifying information will be removed, we will not ask for your additional consent.

WILL I BE PAID FOR PARTICIPATION?

You will receive a $5 e-gift card for filling out the questionnaire at the beginning of the study. You will receive a $5 e-gift card again for filling out the questionnaire at the end of the study.

WILL IT COST ME ANYTHING TO PARTICIPATE?

There is no cost to you for taking part in this study.

WHAT FINANCIAL INTEREST DOES THE RESEARCHER HAVE?

The Institutional Review Board (an ethics committee that helps protect people involved in research) has reviewed the possibility of financial benefit due to this relationship. The Board believes that the possible financial benefit to the researcher is not likely to affect your safety and/or the scientific integrity of the study. If you would like more information, please ask the researchers or study staff.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study, contact the researcher, Cris Henderson, at 812.855.1237.

In the event of an emergency, you may contact Cris Henderson at 317.509.0733.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

CAN I WITHDRAW FROM THE STUDY?

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. If you decide to withdraw, please inform Cris Henderson. The research team will help you withdraw from the study safely. You may provide the reason(s) for leaving the study, but it is not required to provide the reason. You can withdraw at any time without penalty or loss of benefits, to which you are otherwise entitled.

If you decide to withdraw, any member of the research team. Britney Arce at barce@iu.edu and let her know you want to withdraw.

Your participation may be terminated by the investigators without regard to your consent if you do not follow the instructions given to you by the investigator.

PARTICIPANT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study. I will sign the electronic copy of my informed consent document. A signed copy will be emailed to me to keep for my records, and the research team will receive another signed copy. I agree to take part in this study.

Participant's Printed Name:

Participant's Signature: Date: