**Michigan Youth Violence Prevention Center: Building Evidence for Gun Violence Prevention - SafERteens Implementation**

NCT05821205

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# UNIVERSITY OF MICHIGAN
# CONSENT TO BE PART OF A RESEARCH STUDY

## 1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

**Study title:** MI-YVPC SafERteens Implementation Evaluation

**Company or agency sponsoring the study:** Centers for Disease Control and Prevention (CDC)

**Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):**
**Principal Investigator:** Patrick Carter, MD, Department of Emergency Medicine, University of Michigan
**Study Coordinator:** Katy Clark, MA, Department of Emergency Medicine, University of Michigan

### 1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or others about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

Research studies hope to make discoveries and learn new information about certain conditions or social issues and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study, such as time required. In your decision to participate in this study, consider all matters carefully.

This research is studying the implementation of the SafERteens program as part of routine clinical care. The goal is to learn about the best way to roll out the program and sustain it by identifying useful strategies to improve implementation of the SafERteens intervention in health care settings. SafERteens is a brief counseling session for youth reporting recent physical aggression and uses an adaptive motivational interviewing approach to reduce violence outcomes. As a healthcare provider involved in the implementation of SafERteens (screening and/or intervention delivery), you will be asked to complete a brief survey about your training and a baseline survey. There are additional follow-up surveys that you may be asked to complete 3-, 6- and 12-months after your study enrollment depending on when your employment starts or ends at the site and how that coincides with when SafERteens implementation began.

The post-training survey takes about 5 minutes and will ask about your training experience. The other surveys will ask questions about you, your workplace, and experience with evidence-based practices. The baseline survey takes about 30 minutes, and each of the 3-, 6- and 12-month surveys about 20 minutes to complete. You will receive a $5 gift card for completing the post-training survey and a $50

gift card each time you complete the other surveys. The information you provide will be kept confidential.

During the implementation evaluation process, you will also receive a weekly text message about SafERteens to read. The message may contain a testimonial, commitment pledge, or small gift card. The type of message you get each week will be randomized, that is decided by chance, like flipping a coin. Additionally, some months you will receive a text message with personalized feedback about your performance screening or delivering SafERteens. Whether or not you receive this feedback each month will also be randomized.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include breach of confidentiality or discomfort responding to survey questions. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future by setting the stage for future SafERteens dissemination and translation of violence prevention programs. More information will be provided later in this document.

You can decide not to be in this study. Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

## 2. PURPOSE OF THIS STUDY

**2.1 Study purpose:**

This research is studying the implementation of the SafERteens program as part of routine clinical care. The goal is to learn about the best way to roll out the program and sustain it by identifying useful strategies to improve implementation of the SafERteens intervention in health care settings.

## 3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

**3.1 Who can take part in this study?**

Providers aged 18 and older employed at study sites and participating in screening and/or SafERteens delivery are asked to take part in this study.

**3.2 How many people are expected to take part in this study?**

We expect about 240 providers involved in the implementation of SafERteens to take part in this study.

## 4. INFORMATION ABOUT STUDY PARTICIPATION

**4.1 What will happen to me in this study?**

If you decide to join the study, this is what will happen:

- You will be asked to complete a brief 5-minute survey about your training experience in screening and/or delivering SafERteens. You will also be asked to complete a baseline survey with questions about you, your workplace, and experience with evidence-based practices. The baseline survey will take about 30 minutes.

- You will receive a weekly text message about SafERteens to read. The message may contain a testimonial, a commitment pledge, or small gift card. Some weeks you will not receive a message. Whether or not you receive a message and the type of message you receive will be randomized, that is decided by chance, like flipping a coin.
- You will also receive a monthly text message with your personalized feedback related to screening and delivering SafERteens based on information collected from electronic medical records at your site. Whether or not you receive the monthly feedback will also be randomized.
- You may also be asked to complete a follow-up survey at 3, 6 and 12 months depending on when your employment starts or ends at the site and how that coincides with when implementation began. Each follow-up survey takes about 20 minutes.

### 4.2 How much of my time will be needed to take part in this study?

All participants will be asked to complete surveys post-training and at baseline. Some participants will also complete a survey 3-, 6- and/or 12-months after implementation began. The post-training survey takes 5 minutes, the baseline survey about 30 minutes, and the 3-, 6- and 12-month surveys about 20 minutes each to complete.

You may also receive a weekly text message and monthly text message that will only take a few minutes to read.

**4.3 When will my participation in the study be over?**

Your participation in the study may last up to 12 months depending on when implementation of SafERteens began or if you leave employment at your site, whichever comes first.

**4.4 What will happen with my information used in this study?**

Your collected information may be shared with the Centers for Disease Control and Prevention (CDC).

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

## 5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

**5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?**

There is a very small risk that some of the survey questions may make you feel uncomfortable. You may skip any question you don't want to answer, and you are free to end the survey or leave the study at any time.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

**5.2 What happens if I have problems as a result of this research?**

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any problems that you have during this study.

**5.3 If I take part in this study, can I also participate in other studies?**
*Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies*. You should not take part in more than one study without approval from the researchers involved in each study.

**5.4 How could I benefit if I take part in this study? How could others benefit?**
You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study which may help set the stage for future SafERteens dissemination and translation of violence prevention programs.

## 6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

**6.1 If I decide not to take part in this study, what other options do I have?**
Participation in this study is voluntary. If you choose not to participate, your employment at the implementation site will not be affected in any way.

## 7. ENDING THE STUDY

**7.1 If I want to stop participating in the study, what should I do?**
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

**7.2 Could there be any harm to me if I decide to leave the study before it is finished?**
We do not expect that you will experience any harm if you decide to leave the study before it is finished.

**7.3 Could the researchers take me out of the study even if I want to continue to participate?**
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

## 8. FINANCIAL INFORMATION

**8.1 Who will pay for the costs of the study?**
There are no costs for this study. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

**8.2 Will I be paid or given anything for taking part in this study?**
You will receive a $5 gift card after completing the post-training survey and $50 after completing the baseline survey. Participants eligible for the follow-up surveys at 3-, 6-and 12-months will receive $50 for completing each of those surveys. Total potential payment for completing surveys is up to $205.

You will also be randomized to receive $5 gift cards as part of your weekly messages. You could receive up to 13 of these gift cards totaling up to $65.

The highest potential payment any participant could receive between completing surveys and receiving randomized gift cards is $270.

**8.3 Who could profit or financially benefit from the study results?**
Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

## 9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

**9.1 How will the researchers protect my information?**
Research records will be kept in a separate research file that does not include name, email or other information that is likely to allow someone other than the researchers to link the information to you. Unique identification numbers will be assigned to each participant and all data and forms are coded with this number, rather than by name. Your survey responses and individual provider performance data collected from electronic health records will not be shared with hospital/ED/clinic administration or anyone outside of the research. Aggregated department-wide performance data to identify barriers and successes to the program implementation may be shared with administration. Consent forms will be stored separately because they contain identifying information. Electronic data files will be stored on a secure server with restricted access.

The online consents and surveys are designed and administered using the Qualtrics Research Suite through the University of Michigan (https://www.qualtrics.com/research-core/). Qualtrics meets the rigorous privacy standards enforced on health care records by the Health Insurance Portability and Accountability Act (HIPAA). No identifying information is directly linked to your answers. For more information, Qualtrics security and privacy statements can be found at http://www.qualtrics.com/security-statement and http://www.qualtrics.com/privacy-statement.

This research is covered by a Certificate of Confidentiality from the Centers for Disease Control and Prevention. The researchers with this Certificate may not disclose or use information or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information and documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

A description of this study will be available on http://www.clinicaltrials.gov/. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?**
Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
  - Make sure the study is done safely and properly
  - Analyze the results of the study
- **Because you will receive payments for taking part in this study, the University of Michigan accounting department requires that we collect your name, address, social security number, payment amount, and related information for tax reporting purposes.**
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article but would not include any information that would let others know who you are.

**9.3 What happens to information about me after the study is over or if I leave the study before it is finished?**

As a rule, the researchers will not continue to use or disclose information about you but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa.

## 10. CONTACT INFORMATION

**10.1 Who can I contact about this study?**

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report a problem
- Leave the study before it is finished
- Express a concern about the study

**Principal Investigator:** Patrick Carter, MD
Mailing Address: 1109 Geddes Ave 1000 Ruthven, Ann Arbor, MI 48109
Telephone: 734-647-6125

**Study Coordinator:** Katy Clark, MA
Mailing Address: 1109 Geddes Ave 1000 Ruthven, Ann Arbor, MI 48109
Telephone: (734) 992-7087

**You may also express a question or concern about a study by contacting the Institutional Review Board listed below:**

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
*When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.*

## 11. RECORD OF INFORMATION PROVIDED

**11.1 What documents will be given to me?**

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file.)*

## 12. SIGNATURES

**Sig-A**

**Consent to Participate in the Research Study**

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

**Sig-G**

**Principal Investigator or Designee**

I have provided this participant with information about this study that I believe to be accurate and complete. The participant indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

**FOR ELECTRONIC CONSENT**

**12. SIGNATURE**

**Sig-A**

**Consent to Participate in the Research Study**

I understand the information printed on this form. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I can download and save a copy of this consent at the time I sign it and later upon request.

**Do you agree to participate?**

☐ **YES** – I have read and understand the information above and I CONSENT to participate in this study.

Legal Name: _____

Date (mm/dd/yy): _____