UNIVERSITY OF MICHIGAN
ASSENT/CONSENT TO BE PART OF A RESEARCH STUDY

NAME OF STUDY AND RESEARCHERS

Title of Project: Saferteens-PC

Principal Investigator: Maureen Walton, MPH, PHD

GENERAL INFORMATION

Study purpose: We are doing a study to help understand how young people deal with upsetting situations. The purpose of this study is to learn about how health information from the Saferteens-PC program can be shared with 14-18 year olds at the doctor's office, and how this information might prevent behaviors like fighting. What we learn may help us share health information during office visits in a way that is interesting and helpful to young people.

To take part in this study, you must be between the ages of 14 – 18 years old and have filled out the screening survey. We expect about 160 people to take part in this study.

Information about the study: Taking part in this study is completely **voluntary**. You don't have to take part if you don't want to. Your medical treatment in the clinic won't be affected in any way if you decide not to take part. You can also quit the study at any time.

If you decide to be in this research study, this is what will happen:

- While in the doctor's office today, we will ask you to fill out a baseline survey on our tablet computer. The survey will ask questions about your background, how you deal with upsetting situations (e.g., fighting), your health behaviors (e.g., smoking, other substance use), and your contact information. This will take about 15 minutes.
- After the survey, you will be put into one of two groups, based on the date when you join the study:
    - **Group 1**: A member of our study team will review a resource brochure with you. The brochure contains information about local and national services that might be helpful to you. Then, either today or at another day and time that is convenient for you, you will meet with a clinic social worker or other clinic counselor for 30-45 minutes to review your goals, values, and strategies for dealing with upsetting situations. To help set up this meeting, we will let clinic staff know that you qualify for this study. If you have a cell phone with a text messaging plan, you will also receive text messages for two months about the same topics that will be discussed in this meeting. For the first month, you will receive 2-3 text messages each day. Then, for the second month, you will receive 2-3 text messages each week. You can request additional text messages if you would like.
    - **Group 2**: You will only receive a resource brochure with information about local and national services that might be helpful to you. A member of our study team will review the brochure with you.
- About three months from today, we'll contact you to fill out a follow-up survey that will take about 15 minutes. This survey will ask questions about how you deal with upsetting situations,

your health behaviors, and your experience in the Saferteens-PC program. You can complete the survey online, by phone or in-person.

You'll be done with the study once you finish the 3-month follow-up survey.

Payment: To thank you for taking part in our study, you will get $30 for completing the baseline survey and $40 for completing the 3-month follow-up survey. You'll be paid with cash or a gift card. The University of Michigan accounting department may need your name, address, payment amount, and related information for tax reporting purposes. Also, if you are in Group 1 and receive text messages, you may be charged for extra text messages on your personal phone bill if you don't have an unlimited text messaging plan.

Benefits, risks and confidentiality: We don't know for sure if you will be helped by being in this study. However, you could learn new ways to deal with upsetting situations. We hope what we learn will help other people in the future.

It's possible that some of the survey questions may make you feel embarrassed or uncomfortable. If a question makes you uncomfortable, you can just skip it and go to the next question.

There is a very small risk that someone who is not part of this study could find out information about you. We won't share what you tell us with anyone outside of our research team except, if you are in Group 1, clinic staff will receive your screening survey information to help set up your meeting with the clinic counselor for the Saferteens-PC program. All survey answers that you give will be kept private. This is so because this study is covered by a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC). This means that anything you tell us will not have to be given out to anyone, even if a court orders us to do so, unless you say it's okay. But under the law, we must report to the proper authorities suspected cases of child abuse or if you tell us you are planning to cause serious harm to yourself or others.

To protect your information, your surveys will be coded with a unique number and stored in a different location from your name, email address, or any other contact information. Paper forms will be stored in locked file cabinets and computer data files will be kept on secure servers at the University of Michigan and saved with passwords. Any reports or articles that we write won't contain any information that could allow somebody to identify you.

We encourage you to use a password or passcode on your phone to help keep others from seeing study messages on your personal phone. You'll be able to choose what time of day you want to get your text messages. You can also type "STOP" at any time to end the text messages.

The online surveys you will take are designed and administered using 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 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.

The University of Michigan Center for Health Communications Research (CHCR) is in charge of setting up the text messages you'll receive if you are in Group 1. CHCR has a system in place called the Transport Layer Security (TLS) protocol that makes sure information is safely shared. This is the same

system that's used to keep other people from being able to see credit card numbers or other personal details that you enter into a website.

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

This study will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

CONTACT INFORMATION

To find out more about the study, to ask a question or express a concern about the study, or to talk about any problems you may have as a study subject, you may contact one of the following:

Principal Investigator: Maureen Walton, MPH, PhD Mailing Address: 2800 Plymouth Rd. Ann Arbor, MI 48109 Telephone: 734-615-4225 Email: waltonma@med.umich.edu	Study Coordinator: Meredith Kotov, MS, CCRP Mailing Address: 2800 Plymouth Rd. Ann Arbor, MI 48109 Telephone: 734-232-0361 Email: mphilyaw@med.umich.edu

You may also express a concern about a study by contacting the Institutional Review Board:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
734-763-4768
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.

SIGNATURES

Consent/Assent to Participate in the Research Study

I understand the information 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 above. I understand that I will receive a paper copy of this form at the time I electronically sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

If you agree to participate in this study, please click "yes" to the question below to enroll in the study and enter the baseline survey.

Do you agree to participate in the Saferteens-PC research study?

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

Legal Name:_____

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

NO – I do not wish to participate in this study .

Consent for Future Contact: We may contact you again in the future in order to offer you a chance to take part in new research studies. If you're contacted and are willing to participate in a new study, you'll be asked to sign a separate consent form for that study. Your contact information will be kept by the Saferteens-PC research investigators and stored in a password- protected computer data file or locked file cabinet. It will only be available to the Investigators and research staff of the Saferteens-PC study and their future studies. If you have questions, feel free to ask them.

Do you agree to be contacted about future studies?

YES – I CONSENT to be contacted about future studies.

NO – I do not wish to be contacted about future studies**.** I understand that I may still participate in this study, even though I do not want to be contacted about future studies.

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