Informed Consent Form (ICF)

Official Title: Adaptive Interventions to Reduce Risky Drinking and Violent Behaviors Among Adolescents

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UNIVERSITY OF MICHIGAN AND HURLEY MEDICAL CENTER
CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You, or your child, may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study. Parents or legal guardians, who are giving permission for a child, please note: in the sections that follow the word 'you' refers to 'your child'.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title: SafERteens M-Coach (Part 2)

1.2 Company or agency sponsoring the study: National Institutes of Health

1.3 Names, degrees, and affiliations of the researchers conducting the study:

Maureen Walton, PhD – Department of Psychiatry, University of Michigan

Lawrence An, MD – Department of Internal Medicine, University of Michigan

Frederic Blow, PhD – Department of Psychiatry, University of Michigan

Patrick Carter, MD – Department of Emergency Medicine, University of Michigan

Rebecca Cunningham, MD – Department of Emergency Medicine, University of Michigan

Quyen Ngo, PhD – Department of Emergency Medicine, University of Michigan

Kelly Kidwell, PhD – School of Public Health, University of Michigan

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The purpose of this study is to learn more about how young people deal with alcohol and violence. We want to learn how a new prevention program may be helpful for teens and young adults in the Emergency Department (ED). You will answer questions about alcohol use and violence and have the opportunity to receive text messages or talk to a health coach by phone or video calls about your goals and what's important to you and how you deal with these issues. We hope that this project will help us improve prevention programs for teens and young adults who seek treatment in the Emergency Department.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to take part if you don't want to. Your medical treatment in the ED will not be affected in any way if you choose not to take part. You may also leave the study at any time. If you leave the study before it is over, you will not lose any benefits to which you are owed.

3.1 Who can take part in this study?

To take part you must be between the ages of 14 – 20 years old and have a cell phone. If you are 14-17 years old, both you and your parent (or guardian) must agree to you being in the study.

3.2 How many people (subjects) are expected to take part in this study?

We expect about 700 people 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:

- While in the Emergency Department, we'll have you complete the baseline survey. You'll answer part of the questions on our tablet computer and this takes about 30-40 minutes. Some questions will be answered with our research staff and will take about 15 minutes. The questions ask about fighting, violence and health behaviors including alcohol and drug use.
- After the survey, you'll have a private 30 minute meeting with a health coach to review the prevention program and talk about your goals, values, thoughts about violence and violence related issues, alcohol and drug use. The session will be audiotape recorded (voice only) and you can give your permission for the later in this form.
- You will then be **randomly** put into one of two groups (random means by chance, like "flipping a coin"):

  Group 1: After you leave the Emergency Department today, each Sunday for the next 8 weeks, you'll be sent a text to remind you to fill out a short 5-10 minute weekly survey that can be done online, over the phone, or in-person. You'll then start getting daily text messages with encouragement, support, and tips to handle stress of everyday life. After week 4, you'll either keep getting text messages for 4 more weeks or you'll change to no more text messages and you'll get a health brochure or you'll change to getting once a week phone or video chat meetings with the health coach that will last about 15-30 minutes. You can talk to the health coach by phone or you can pick whatever video chat platform you want to use (for example, UM Zoom, UM Google meets, VSee, Vidyo, Messenger, Skype, FaceTime). The health coach will talk with you about your goals, values, thoughts about violence and violence related issues, alcohol/drug use and this will be audiotape recorded.

  Group 2: After you leave the Emergency Department today, each Sunday for the next 8 weeks, you'll be sent a text to remind you to fill out a short 5-10 minute weekly survey that can be done online, over the phone, or in-person. Then the health coach will call or video chat with you once a week to continue talking about your goals, values, thoughts about violence and violence related issues, alcohol/drug use. You can talk to the health coach by phone or you can pick whatever video chat platform you want to use (for example, UM Zoom, UM Google meets, VSee, Vidyo, Messenger, FaceTime or Skype). These sessions will last about 15-30 minutes and will be audiotape recorded. After week 4, you'll either keep having weekly talks with the health coach for 4 more weeks or the health coach will start contacting you more often than once a week or you'll change to no more contact with the health coach and you'll get a health brochure.
- At about 4-months and again at 8-months from the time that you first signed up for the study, we will contact you to fill out another survey. Like the baseline survey, you'll answer part of the

questions on our tablet computer that will take about 45 minutes. Some questions will be answered with our research staff and will take about 15 minutes. The questions ask about fighting, violence and health behaviors including alcohol and drug use. We'll try to meet with you in person for the 4 and 8 month follow-up visits. We can meet at Hurley Medical Center, your home or any other convenient location. But if you can't meet with the research staff in person for any of these appointments, the surveys can be done using an online survey and on the phone with research staff. For telephone interviews, the research staff member will read the questions from the survey and enter your answers. For online surveys, you'll get an email invitation with a link and password to enter the survey (see section 9 for information about online survey security and privacy).

- Finally, we will look at your medical record at Hurley Medical Center to get information about number of Emergency Department visits you've had, reason for visit, medications, and days of hospitalization during the time from one year before you joined the study to one year after.
- If you're under age 18 and become an adult (turn 18 years old) while you are in this study, we'll ask you if you want to continue to be in this study as an adult and have you give your consent again.

4.2 How much of my time will be needed to take part in this study?
Today it will take about 1 ½ hours to learn about the study, complete the baseline survey and meet with the health coach. During the next 8 weeks, weekly Sunday surveys will take about 5-10 minutes. Reading daily text messages will take about 5 minutes of your time each day. Phone/video chat sessions with the health coach will last about 15-30 minutes once a week. The 4 and 8 month follow-up surveys will each take about 50-60 minutes.

4.3 When will my participation in the study be over?
You'll be done with the study after your 8-month follow-up visit but we will continue to collect information from your Hurley medical record up to 1 year from the time you joined the study.

4.4 What will happen with my information used in this study?
Your collected information may be shared with the National Institutes of Health.

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 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?
Some of the questions we ask are about sensitive or personal information such as violence and your alcohol or drug use. Sometimes these questions can make you feel embarrassed, uncomfortable, or upset. You don't have to answer any questions you don't want to and you can leave the study at any time. You can also type "STOP" at any time to end the text messages.

There is a small risk of loss of privacy/confidentiality. To protect your privacy during in-person and telephone meetings we will make sure that no one can overhear the conversation. We will ask you to have others leave the room during sessions. We encourage you to use a password or passcode on your phone to help with the privacy of the study messages on your personal phone. You'll be able to choose what time of day you want to get your text messages. You will get reminders to delete your text

messages after you answer your surveys so nobody can accidentally see them. We will do everything we can to protect your identity and keep your answers confidential, except as noted in section 9.1. Parents will agree not to ask questions about their child's survey answers and the study team will not share answers with parents/guardians. When your survey answers and audio files are collected, they are labeled with a number. Survey answers and audio files are stored separately from your name, phone number, email address or other information that might let someone other than the researchers connect the information to you. You will be asked during sessions to try not to say your name or any information that would allow someone to determine who you are from the audio recording. Study paper forms are stored in locked file cabinets. Computer files are saved with passwords. You will not be identified in any reports on this study.

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

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to reduce the risks of this study. 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. Some people may find that answering the survey questions is helpful. You may learn more about violence, alcohol use and other health behaviors. We hope to use our results to improve prevention programs for teens and young adults who seek treatment in the Emergency Department.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change whether you want to stay in this study. If new information is given to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?
Participation in this study is voluntary, which means you don't have to take part in the study if you don't want to. If you choose not to participate, it will not affect your medical care 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" (below).

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 would 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.
- ✓ Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- ✓ 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? Will I or my health plan be billed for any costs of the study?
Taking part in this study will not cost you anything. You may be charged for texting by your phone company. As with any cell phone, if you don't have an unlimited texting or data plan, you may be charged for texting or data use on your personal phone bill.

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 get cash or a gift card after completing each study activity listed below.

Study Activity	Amount
Baseline survey	$40
Sunday text message survey ($10 x 4 for weeks 1-4)	$40
Sunday Text message survey ($15 x 4 for weeks 5-8)	$60
4-month survey	$40
8-month survey	$40
	Total: $220

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 AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?
You may be worried about the privacy of your answers. We won't share your answers with anyone except the researchers of this study. We will ask for your contact information so that we can contact you

about the study. This personal information will not be connected to any of your survey answers. Your surveys are coded with a unique ID number and stored in a file that is separate from your name, email address, or any other contact information. Paper documents are stored in locked file cabinets and computer data files are kept on secure servers and saved with password protection. Any reports or articles that we write will not have any information that could allow somebody to identify you. Limited data may continue to be used after the study is over, for other research, education, or other activities, but use of this information would not reveal your identity.

The computerized surveys are designed and administered using Qualtrics Research Suite through the University of Michigan (http://www.qualtrics.com/). Qualtrics meets the rigorous privacy standards imposed on health care records by the Health Insurance portability and Accountability Act (HIPAA). There are security precautions in place to protect against unauthorized access, but there is still a small risk of unauthorized access. 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) will be responsible for programming and setting up the text-messaging system. To ensure that the data are protected, CHCR uses virtualized servers provided by the University of Michigan Information Technology Services group. When a participant accesses the study website, content is transmitted securely using the Transport Layer Security (TLS) protocol, the same protocol used to protect financial and other personal information when transmitted from a web site to a user's browser. This prevents anyone else on the network from intercepting and viewing the content that is being provided by or to the participant.

Your confidentiality will be kept to the degree permitted by the technology being used. Although every reasonable effort has been taken, confidentiality during actual web-based or phone communication procedures cannot be guaranteed.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. 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, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects. The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the NIH which is funding this project. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. 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. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse or harm to self or others.

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. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- All records relating to your ED and hospital visits, the treatment you have received, and your response to the treatment
- Personal identifiers, such as your contact information

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
  - Learn more about side effects
  - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need 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.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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.

9.3 What happens to information about me after the study is over or if I cancel my permission?

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. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

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 activities
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Maureen Walton, PhD		**Study Coordinator**:	Carrie Bourque, MS
Mailing Address:	2800 Plymouth Rd. Ann Arbor, MI 48109	Mailing Address:	1 Hurley Plaza, SON Flint, MI 48503
Telephone:	734-615-4225	Telephone:	734-232-0406

You may also express a 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
Telephone: 734-763-4768
Fax: 734-763-1234
e-mail: irbmed@umich.edu

Hurley Medical Center
Institutional Review Board
1 Hurley Plaza
Flint, MI 48503-5993
Telephone: 810-262-9974
Fax: 810-262-9587

If you are concerned about a possible violation of your privacy, contact the Hurley IRB at 810-262-9974 and/or University of Michigan Health System Privacy Officer at 1-888-296-2481.

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.)*
- Other (specify):_____

12. SIGNATURES

Consent/Assent 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 _____. My questions so far have been answered to my satisfaction. 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. 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.

Legal Name: _____

Signature: _____

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

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

Legally Authorized Representative or Parent Permission

Subject Name:_____

Parent/Legally Authorized Representative:

Name:_____

Signature: _____

Address: _____

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

Relationship to subject: Parent Spouse Child Sibling Legal guardian Other

If "Other," explain: _____

Reason subject is unable to consent: _____

Audio-Taping Consent: I agree to be audiotape recorded (voice only) as a subject in this research study. I also agree that the recording may be used for the purpose of this research. I understand that I can stop the recording at any time. I can still be a part of this study if I don't want to be recorded. If you have questions, feel free to ask.

Please initial here if you agree to be audiotaped.

Your initials: _____ Your parent(s) initials (if under 18): _____

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Legal Name: _____

Title: _____

Signature: _____

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