Informed Consent Form (ICF)

Official Title: Optimized Interventions to Prevent Opioid Use Disorder Among Adolescents and Young Adults in the Emergency Department

Document Date: 11/20/2023

NCT number: NCT04550715

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

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Check-In Study

Agency sponsoring the study: National Institutes of Health

Principal Investigators:
Maureen Walton, MPH, PhD – Department of Psychiatry, University of Michigan
Erin Bonar, PhD – Department of Psychiatry, University of Michigan

Study Coordinator:
Meredith Kotov, MS, CCRP – Department of Psychiatry, University of Michigan

1.1 Key Study Information

You, or your child, may be eligible to take part in a research study. Parents or legal guardians who are giving permission for a child's participation in the research, note that in the sections that follow the word 'you' refers to 'your child'.

This form contains information that will help you decide whether to join the study. All of the information in this form is important. Take time to carefully review this information. After you finish, 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 friends, family, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you do, be sure you understand what the study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about certain conditions 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 don't always offer the possibility of direct benefit. 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 of these matters carefully.

This research is studying new ways of sharing health and wellness information with young adults. Researchers want to understand how best to share this information so it will be interesting to people around your age. You will be first asked to complete a baseline survey and provide contact information, such as your phone number, email, and social media. We may also contact you using information that we find in publicly available sources. Then, you may be asked to complete a video chat meeting with a study health coach, receive a community resource brochure, and/or enroll in an online portal where you can exchange messages with your health coach over the next 4 weeks. Then, in 3-, 6- and 12- months, you will be asked to complete another survey, either in-person or remotely. You can earn up to $210 for completing all study activities.

This study involves a process called randomization. This means that the group you are assigned to is not chosen by you or the researcher. The study design divides study participants into separate groups based on chance (like the flip of a coin), to compare the different programs.

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 potential loss of confidentiality or feelings of discomfort as a result of being asked personal questions. More detailed information will be provided later in this document.

This study may offer some benefit to you now or others in the future by sharing new health information that could be helpful. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be about one year. Your participation in this study will be over after you complete your 12-month survey.

You can decide not to be in this study. Participation is completely voluntary.

Even if you choose 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:

We're doing a study to learn more about ways to share health and wellness information with people your age. The purpose of the study is to test prevention methods to promote wellness and reduce risky behaviors, including use of substances such as alcohol, opioids, and other drugs. The study will help us to learn about ways of delivering this information that is both appealing and helpful to young adults.

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?

To take part in this study, you must be between 16 to 30 years old and qualified by completing the screening survey. If you are 16-17 years old, both you and your parent (or guardian) must agree to you being in the study.

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

Approximately 1280 people are expected 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, you will be asked to complete the baseline survey while in the Emergency Department (ED). This will take about 20-25 minutes. The survey will ask you questions about your background and health behaviors, including alcohol and drug use, doctor visits and prescription medications.

From here, you will be randomly assigned (like tossing a coin) to one of four study groups so we can test the effectiveness of different health interventions. The four study groups are:

1. Check-In Session + Check-In Portal – First, you would complete a brief (~30-40 minute) video-chat session with one of the health coaches from our study team. The health coach will privately discuss goals, strengths, and challenges, along with strategies for overcoming those challenges. The session will be audio recorded (voice only) and you can give your permission for that later in this form. You may still take part in the study if you don't want to be audio recorded. Then, you will be enrolled in the Check-In Portal, where you'll be able to communicate with the health coach over the next 4 weeks. You will receive messages on the portal and via text/email from the health coach about topics discussed in the video chat session. For those in the Check-In Portal and/or Check-In Session: Your story and openness are so important, and we are honored to have the opportunity to listen. We strive to create a space of curiosity, tolerance and respect and thank you for being part of it.
2. Check-In Session + Resource Brochure at 4 weeks – First, you will have a video-chat session with a health coach as described above. Then in 4 weeks we will send you a community Resource Brochure.
3. Resource Brochure + Check-In Portal – First, study staff will provide you with a community Resource Brochure today. Then, you will be enrolled in the Check-In Portal as described above.
4. Resource Brochure + Resource Brochure at 4 weeks – First, study staff will provide you with a community Resource Brochure today. Then in 4 weeks we will send you another copy of the community Resource Brochure.

Then, in 3-, 6-, and 12-months from today, we will ask you to complete follow-up surveys, with questions similar to those in the baseline survey.

The follow-up visits can be completed in-person, over the phone or online. For telephone interviews, the research staff member will read the questions from the survey and enter your answers. For online follow-up surveys, you'll get an email invitation with a link and password to enter the survey. Agreeing to this study also gives permission for the study team to look at your University of Michigan medical record and your prescription history from the State of Michigan Prescription Program for the year before and the year after you join this study. We will collect information such as your healthcare visit history, reason for each visit, and what medications you have been prescribed and had filled. Information from today's visit will be used by the health coach to tailor information that you could receive in the video session or portal messaging.

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's baseline survey will take approximately 30 minutes. If you are also asked to complete a video meeting with a health coach today, it will take approximately 30-45 minutes. The amount of time you spend on the portal is up to you. The 3-, 6-, and 12--month follow-up surveys will each take approximately 25-30 minutes of your time.

4.3 When will my participation in the study be over?
You will be involved with the study for about 12 months. After completing the 12-month follow-up survey, your participation in the study will be over.

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.

The information that we collect from you will be stripped of identifiers (meaning any of your personal information, such as name or email) and used for future research studies or distributed to another researcher for future research studies without additional informed consent. The study sponsor, the National Institute of Drug Abuse (NIDA) of the National Institutes of Health, requires that we share your de-identified data with other researchers to help learn how to prevent opioid use and misuse. Study staff will remove all personal information before any data files are transferred to the repository. Your de-identified data will be protected, following laws that protect the use of health information, and studied only for health research purposes.

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?
The known or expected risks are feelings of discomfort as a result of being asked personal questions and loss of confidentiality.

Some of the questions that will be asked are about sensitive or personal information such as your alcohol or drug use. These questions may make you feel uncomfortable or nervous. You may skip questions you don't want to answer, however, some questions require response in order to continue in the study and receive payment for your survey. You are free to leave the study at any time.

There is a small risk that others in the ED may overhear information during your baseline activities or see survey information on the tablet. To protect your privacy during your baseline activities in the ED and video chat session with the health coach, we will make sure that no one can overhear the conversation, including having you use headphones during the session. We will have others leave the room during the session. Study tablets have privacy screens so that others cannot see what's on the tablet.

It is possible that, if you access your patient portal or remotely complete your surveys on a device that others can access (e.g., a public computer), the next person who uses the device could unintentionally see your messages or survey answers. To protect your privacy, please clear your browsing history and/or delete any received text messages or emails after using a non-private device to access any information relevant to this study.

It is important that you know we will not share your survey answers with anyone, however, we may be required by law to report to appropriate agencies if we learn about such things as child abuse or harm to self or others (suicidality or homicidality). We will let you know if we need to make a report. If you are a minor and we learn that you are at risk of harming yourself (suicide), we may also contact your parent or guardian. No guarantees can be made regarding third-party access to data sent via internet or phone.

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 get hurt, become sick, or have other 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.

Some people find completing the surveys to be helpful. We will share information about community and national resources with you, which you may find to be beneficial. We hope to learn more about ways to deliver health information to young people and adults as a result of this study.

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 your willingness to stay in this study. If new information is provided 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. 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 the study is entirely voluntary. If you decide not to take part, your medical care 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?
It is not expected that any harm would be done to you 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?

There are no costs or billing 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?

To thank you for taking part in our study, you will get $50 for completing the baseline procedures. You will receive $50 for completing the 3-month follow-up survey, $50 for completing the 6-month follow-up survey, and $60 for completing the 12-month survey. You will be paid in cash or e-gift cards via Amazon within about 7 days after you complete the study activities for each time point.

8.3 Who could profit or financially benefit from the study results?

No person or organization has a financial interest in the outcome of this study. 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 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?

To protect your information, research records will be kept in a separate research file that does not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you. Your surveys and audio recordings will be coded with a unique number and stored in a different location from your name, email address, or any other contact information, which will be collected only to contact you about the study. 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. Audio recordings will be collected using a digital recorder and sessions will be immediately uploaded to a password protected server and deleted from the recorder. We will always ask your permission before any audio recording. 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. Any reports or articles that we write won't contain any information that could allow somebody to identify you.

Your personal information will be kept in Ripple™, a secure web application designed for the storing and management of personally identifying information of research participants. Information managed with Ripple is private, secure and encrypted. Only authorized study staff will have access to your information.

Ripple infrastructure complies with the privacy and security guidelines of the Health Insurance Portability and Accountability Act (HIPAA). Ripple is used only for storing personally identifiable information of study participants and is not used to capture other research data (e.g., surveys, health records, etc.). This ensures that the personally identifiable information and research data are separated.

The online surveys are designed and administered using Qualtrics Research Suite (http://www.qualtrics.com/) through the University of Michigan. Qualtrics is dedicated to protect all customer data using industry best standards. There are security precautions in place to protect against unauthorized access, but there is still a small risk of unauthorized access. There are systems in place that prevent the survey from being taken more than once. 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.

We will use a video chat platform (e.g., Facetime, Vidyo, BlueJeans, Zoom, or Skype for Business) for your session with the health coach. Your confidentiality will be kept to the degree permitted by the technology being used. If a platform is used which is not affiliated with the University of Michigan (i.e., Facetime), it is possible that you could be automatically recorded by the platform – similar to when you use these platforms in everyday life. Although every reasonable effort will be taken, confidentiality during actual web-based or video chat communication procedures cannot be guaranteed.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

A description of this clinical trial 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 protected health information (PHI) 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.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called

protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital records, including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information (e.g., race, ethnicity, gender)
- Personal identifiers

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.
- The researchers may need the information to check your test results.
- 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.

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 left the study 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 to use my PHI 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). If you withdraw your permission, you may no longer be eligible to participate in this study.

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: Maureen Walton, PhD, MPH
Email: waltonma@med.umich.edu
Telephone: (734) 615-4225

Principal Investigator: Erin Bonar, PhD
Email: erinbona@med.umich.edu
Telephone: (734) 764-7936

Study Coordinator: Meredith Kotov, MS, CCRP
Email: mphilyaw@med.umich.edu
Telephone: (734) 232-0361

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
Telephone: 734-763-4768
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 the following document:

- 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/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 [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. 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.

Print Legal Name: _____

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

Signature: _____

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

Sig-B

Consent/Assent to audio recording solely for purposes of this research

This study involves audio recording which will only be used by the study team for internal quality assurance purposes. Please sign below if you agree to be recorded. If you do not agree to be recorded, you CAN still take part in the study.

Print Legal Name: _____

Signature: _____

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

Sig-E

Legally Authorized Representative or Parent Permission

Subject Name: _____

Parent/Legally Authorized Representative:

Printed Legal Name: _____

Signature: _____

Address: _____

Cell phone number: _____

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: _____

If this consent is for a child who is a ward of the state (for example, a foster child), please tell the study team immediately. The researchers may need to contact IRBMED.

Sig-B

Consent audio recording solely for purposes of this research

This study involves audio recording which will only be used by the study team for internal quality assurance purposes. Please sign below if you agree that your child can be audio recorded. If you do not agree to audio recording, your child CAN still take part in the study.

Print Legal Name: _____

Signature: _____

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

Sig-B

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.

Printed Legal Name: _____

Title: _____

Signature: _____

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