INFORMED CONSENT DOCUMENT

Official Title: Adaptive Interventions for Prevention/Intervention for Youth Substance Abuse

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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: MiSARA

Company or agency sponsoring the study: University of Michigan

Principal Investigator: Maureen Walton, MPH, 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 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 contact the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family or friends 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 and how to treat them. You should consider the reasons why you might want to join a research study or why it might not the best decision for you at this time.

Research studies don't always offer 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 amount of time required. In your decision to participate in this study, consider all of these matters carefully.

This research is studying whether changing a person's behaviors may have an effect on health behaviors such as substance use. This research will study substance use behaviors among 16-24 year olds. You will be asked to complete a baseline survey and then download an app on your smartphone which will deliver daily push notifications for 30 days. We will ask you to complete another survey at the end of that 30 days. Information about things such as your stress, substance use and mood will be collected for this research study. You can earn up to $63 in e-gift cards and the study will last 1-2 months.

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 feelings of discomfort answering personal questions on sensitive topics, and loss of confidentiality. 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 allowing us to better understand how to deliver appealing and helpful interventions using a mobile phone app. More information will be provided later in this document.

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:

The purpose of this study is study to learn more about how cell phone apps can be used to collect and share health information. We are asking 16-24 year olds to help test a new phone app named MiSARA and provide feedback about the app's features and usability. This feedback will be used to refine and improve the app.

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 allowed.

3.1 Who can take part in this study?

To take part in this study, you must be between the ages of 16 – 24 years old and have qualified for the study based on your eligibility survey answers about your health behaviors and the type of cell phone you have.

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

We expect about 40 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, we will ask you to complete a 20-25 minute baseline survey and provide additional contact information. The survey will ask questions about how you cope with stress, your health behaviors (e.g., smoking, other substance use) and social relationships. Then, you will receive instructions about how to download and use the MiSARA app on your personal phone.

For a period of 30 days (called the “app testing period”), the MiSARA app will automatically collect data about your interaction with the app, movement and GPS location. During this period, you will be asked to complete three types of tasks within the app: brief (2-3 minutes) daily surveys, short (5-10 minutes) weekly surveys, and daily active tasks (1-2 minutes each). You will earn points for completing these tasks that can be used to unlock new fish for a virtual aquarium in the app. You can also earn money for interacting with the MiSARA app during the app testing period. The amount earned will vary by chance and how many tasks you complete. You will receive daily push notification reminders about completing surveys and active tasks. We may also contact you by phone, email, and/or social media with reminders. You will also receive messages and images within the MiSARA app that include references to health behaviors, including smoking and alcohol/drug use.

One month after you enroll in the study, you will be asked to complete a follow-up survey that will take about 35-45 minutes. The survey will ask about your health behaviors, experience using the app, and feedback about app content. The survey can be completed online, by phone, or in-person.

4.2 How much of my time will be needed to take part in this study?
The baseline survey will take about 20-25 minutes to complete. The amount of time you spend using the app during the 30 days of app testing is up to you. The 1-month follow-up survey will take about 35-45 minutes.

4.3 When will my participation in the study be over?
Your participation in the study will be over after you complete the 1-month follow-up survey. Although certain features of the app will be deactivated after the end of the 30-day app testing period, you may keep the app installed on your phone after the study ends if you would like

4.4 What will happen with my information used in this study?
Your collected information may be shared with the sponsor of this study (National Institutes of Health). Your collected information may also be shared with other researchers, here, around the world, and with companies but only if you sign a new consent for that research.

The information we collect from you may be stripped of identifiers (meaning any information that would identify you, like name or email, would be removed) 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?
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 anxious. You may skip any question you don't want to answer and you are free to 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. Some people may find that answering survey questions is helpful. By viewing the app content, you may learn more about substance use and other health behaviors. You will also receive information for national and community resources,

including crisis hotlines and substance use and mental health treatment services. We hope this study will help us better understand how to deliver appealing and helpful interventions using a mobile phone app.

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 this study is voluntary. Choosing not to participate will not affect you 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 allowed. 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 email misarasquad@med.umich.edu or 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 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.
- 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. You may get data charges from your phone company for using the MiSARA mobile phone app. As with any other phone app, if you do not have an unlimited data plan or do not connect your phone to Wi-Fi, you may be charged for data usage 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 receive a $20 e-gift card for completing the baseline survey and downloading the app on your phone. During the 30-day app testing period, you can earn a maximum of $13 for interacting with the app ($1 for completing your first survey and two active tasks; $1 for each 3-day streak of completing your survey and two active tasks each day; and an additional $0.50 for each weekly survey completed). You will receive an e-gift card at the end of the 30-day app testing period with all money earned from interacting with the app. You will also receive a $30 e-gift card for completing the 1-month follow-up survey. The total amount of money you can earn is $63.

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. The investigators and University of Michigan may eventually license and sell the app. This means that they and the University of Michigan might one day gain financially from this study. 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 described in this document.

9.1 How will the researchers protect my information?
You may be worried about the privacy of your answers. We won't share your answers with anyone except the researchers of this study. If you qualify for the study and are interested in participating, we will ask for your contact information so that we can contact you about the study and send your electronic gift cards. This personal information will not be connected to any of your survey answers. Your surveys will be coded with a unique ID number and stored in a file that is separate from your name, email address, or any other contact information. Computer data files will be kept on secure servers at the University of Michigan and saved with password protection. Any reports or articles that we write will not contain any information that could allow somebody to identify you.

The computerized surveys are designed and administered using Qualtrics Research Suite through the University of Michigan (http://www.qualtrics.com/). 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. 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.

All data collected through the MiSARA app will be regularly uploaded to a secure computer server. These data will rest on your phone within the app when internet connection is not available. Data will be encrypted before being stored locally on your phone and/or transmitted to the server. We strongly encourage you to set a security passcode or TouchID on your phone in order to protect all locally stored data. The MiSARA app will not collect or store your full name or contact information; all data stored on the server will instead be coded with your unique ID number. Data will be stored on the server until we complete the study.

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 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. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of suspected cases of child or elder abuse or neglect or if you tell us you are planning to cause serious harm to yourself or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

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

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
    - 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, payment amount, and related information for tax reporting purposes.

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 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.

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.)

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 or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Maureen Walton, MPH, PHD Mailing Address: 2800 Plymouth Road, Building 16 Ann Arbor, MI 48109 Telephone: 734-615-4225 Email: waltonma@med.umich.edu	Study Coordinator: Meredith Kotov, MS, CCRP Mailing Address: 2800 Plymouth Road, Building 16 Ann Arbor, MI 48109 Telephone: 734-232-0361 Email: mphilyaw@med.umich.edu

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 (For International Studies, include the appropriate calling codes.)
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 consent 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.)*

Please click here to save or print a copy of this consent form.

12. SIGNATURES

Consent/Assent 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 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. **I understand that in order to participate in this study I must download the MiSARA app and accept push notifications for the month of the 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 MiSARA research study?

YES – I have read and understand the information above. I am between the ages of 16 and 24 years old, and I CONSENT to participate in this study.

Legal Name: _____

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


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