

## **Informed Consent Form (ICF)**

**Official Title:** Social Media Interventions to Reduce Alcohol Use Among Youth

**Document Date:** 12/11/2019

**NCT number:** NCT02809586

## UNIVERSITY OF MICHIGAN

### CONSENT TO BE PART OF A RESEARCH STUDY

#### INFORMATION ABOUT THIS FORM

You 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.

Please take time to review this information carefully. After you have finished, you should communicate with the research team or e-coaches about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends parents or other family members) 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:

Project Amaze

##### 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

Jose Bauermeister, PhD, School of Nursing, University of Pennsylvania

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

Amy Bohnert, PhD, Department of Psychiatry, University of Michigan

Erin Bonar, PhD, Department of Psychiatry, University of Michigan

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

Marc Zimmerman, PhD, School of Public Health, University of Michigan

#### 2. PURPOSE OF THIS STUDY

##### 2.1 Study purpose:

In this research study we are trying to better understand how young people are using social media, in particular Facebook, and how social media affects behavior and other aspects of young peoples' lives. The purpose of the study is to develop and test social media interventions to help young people reduce risky behaviors, such as alcohol use. The study will help us learn about ways to deliver wellness information in a way that is appealing and helpful to young people who use Facebook.

#### 3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

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 the ages of 16 – 24 years old and qualified for the study by completing the short eligibility survey.

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

We expect about 900 people who are 16-24 years old 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 45-60 minute baseline survey. The survey will ask questions about your social media use, interactions with your friends, and health behaviors including alcohol and drug use, and injury. After completing the survey, you will be asked to submit a 'selfie' where you hold up a homemade sign with the current date and time. The Amaze staff will use your selfie to be sure you are who you say you are by checking your selfie picture against your Facebook profile pictures. If you don't submit a selfie or if study staff can't confirm your identity, you won't be able to continue in the study. You must also agree to follow the rules of the Facebook Group User Safety Agreement (below). If you are a minor, we encourage you to let your parents or adult guardian know you are participating in this study. Of course, this is your choice.

Once we confirm your identity, you will be randomly assigned (like flipping a coin) to one of the study groups and asked to join the secret Facebook page for that group for 8 weeks. You will also receive a friend request from an e-coach. The groups will be divided by age (16-20 year olds, and 21-24 year olds). The groups are:

**Group 1:** You will have access to the secret Facebook page that will deliver health information focused on reducing risky behaviors, including alcohol use. This information will be posted by e-coaches. You can interact with the e-coaches as well as other study members in your group. For this group, you will earn "points" for interacting on the group page (for example: "Shares", "Posts" and "Comments" related to the content of the group page) and be paid for the points you earn.

**Group 2:** You will have access to the secret Facebook page that will deliver health information focused on reducing risky behaviors, including alcohol use. This information will be posted by e-coaches. You can interact with the e-coaches as well as other study members in your group. This group does not earn points.

**Group 3:** You will have access to the secret Facebook page that will share news information about things like entertainment, sports, weather and world news. This group does not earn points.

We'll send you weekly reminders to check out the secret Facebook group page during the 8 weeks. You will be asked to complete 3 surveys during the next year. These surveys will be done at 3-months, 6-months, and 12-months from the time that you first joined the study. Surveys will ask the same kinds of questions as the baseline survey and will take about 45 minutes to complete. When it's time for your follow-up surveys, you'll receive an email or text invitation with a link and password to access the surveys. Finally, we will look at your Facebook profile at baseline, 3, 6 and 12 months and count the kinds of posts, comments and pictures that are posted on your page.

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

The baseline survey will take about 45-60 minutes to complete. The amount of time you spend during the 8 week secret Facebook group is up to you. The 3, 6 and 12-month surveys will each take about 45-60 minutes of your time.

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

Your participation in the study will be over after you complete the 12-month follow-up survey.

**\*\*\*FACEBOOK GROUP USER SAFETY AGREEMENT\*\*\***

We want to keep each other safe, so by agreeing to join the study you will be agreeing to the following safety rules. If you begin the study and then later choose not to follow these rules, your ability to interact within the group page may be removed.

**Get Involved** You'll likely get the most out of this experience through interaction, liking posts and comments, posting to the page, and commenting on other group members' posts.

**Keeping Your Info Undercover** The secret Facebook pages will not contain any of your survey responses or contact information. All interaction and content (i.e. likes, posts, comments) in the group will be viewable to other participants in the group, but will be secret to others outside the group; meaning all of your other 'Friends' on Facebook will not be able to view the group, or search for it, or know that you are a member of it (i.e. it will not appear on your list of 'Groups' on your profile).

**Shut it Down** Please close your Facebook webpage if you walk away from your device; leaving it open and viewable could show the private content of the group to others.

**Keeping it Real (and Relevant)** Posts and comments should be relevant to or related to questions or statements about the topics/discussions which have been presented.

**Keep It On The Down Low** If you see someone from the group somewhere else online or have met in real life, you may not discuss their membership in this group with, or in front of, other people (in person or online). Please respect the other person's right to privacy.

**Making Friends** You can "friend" other members of the group on your personal Facebook pages; you are also allowed to decline or ignore friend requests from other group members or e-coaches.

**Don't Yuck Someone Else's Yum** Be respectful of others' opinions and respect that we are all different. Derogatory and degrading interactions, name calling, insults, and trolling will not be tolerated.

**Just Don't Go There** Posting comments regarding the following are **prohibited**: 1) asking for or telling others where to find drugs/alcohol; 2) advertisements for a business; 3) graphic or disturbing photos, videos or other media. If you're not sure about something that you want to post, email us at [Amaze-Crew@med.umich.edu](mailto:Amaze-Crew@med.umich.edu).

**Two Strikes and You're Out.** If any of these terms are violated, the e-coach will privately contact anyone involved. The first violation will result in a warning and a reminder of this agreement. A second violation will result in a restriction of your ability to participate in the group and you will no longer be able to earn points.

**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 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.

There is also a risk of loss of privacy/confidentiality. Every effort will be made to protect your identity. Your survey information will not be shared with anyone except for authorized study staff (except as described in section 9 below). When your survey answers are collected, they are labeled with a number. Survey answers are stored separately from your name, phone number or email address. Study materials are stored in a locked facility and in secure computer files. Secret Facebook group pages will be viewable by staff and other study members in that group. This means that others in the group may see your profile name and profile information depending on your personal privacy settings. All study members must agree to follow the rules of the User Safety Agreement to help protect everyone's privacy. Although all participants must agree to follow these rules and violations will be taken seriously, it is possible that another participant in the secret group may not adhere to the rules and share your

private information with others outside the group. We have also obtained a Certificate of Confidentiality which helps make sure that all your identifying information remains confidential.

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. Some people may find that answering the survey questions is helpful. In the secret Facebook group page, you may learn more about alcohol use and other health behaviors. The study website and Facebook group pages will contain information on national resources including crisis hotlines and resources for substance use and mental health treatment. We hope this study will help us understand ways to deliver appealing and helpful interventions through social media.

### **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. 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. If you choose not to participate, access to your Facebook account 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" (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?

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?

You will get an e-gift card after completing each study activity listed below. You must finish each survey to receive your gift card, but you can still skip any question you don't want to answer.

Study Activity	E-gift Card Amount
Baseline survey, selfie verification, and join secret Facebook page	\$30
3-month survey	\$35
6-month survey	\$45
12-month survey	\$55
	Total: \$165

If you are in Group 1, you will also get \$1 for each day you interact (i.e. - posts/comments/shares related to the content of the group page) on the Facebook group page. You can get a maximum of \$7 per week over the 8 weeks for an additional \$56. Group 1 study total will be \$221.

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

No person or organization has a financial interest in the outcome of the study, including Facebook.

## 9. CONFIDENTIALITY OF SUBJECT RECORDS

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, but if we learn about child abuse, or that you are at risk of harm to yourself (suicide) or others (homicide), we may have to notify the authorities or parents of minors. We will ask for contact information so that we can contact you about the study and to 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 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. Your 'selfie' will not be connected to any of your information. We will destroy your selfie when your Facebook group ends at 8 weeks. Here is additional information about Facebook and Privacy information:

- We will provide you with instructions on how to locate your privacy settings in the event that Facebook changes their privacy settings.
- The Facebook group pages will be secret and confidential, meaning only members of the secret group can view the group; all of your other friends on Facebook will not be able to view the group, or search for it, or know that you are a member of it (i.e. it will not appear on your list of 'Groups' on your profile).

- The researchers will not download information from any individuals' Facebook pages or profiles.
- We encourage you to close out of the Facebook webpage when you are not using it; although you will not be able to add other people to the secret Facebook group page, leaving the webpage or device open could unintentionally show the content to others.
- Information on Facebook Privacy Policies can be found at: <https://www.facebook.com/about/privacy>

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 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>.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, 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 if we learn of information about suspected or known sexual, physical, or other abuse of a child or older person, or threats of violence to self or others. If any member of the research team is given such information, he or she will make a report to the appropriate authorities. 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.

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 projects. 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 you release information identifying another participant as a subject in the study, or another participant identifies you, this may cancel the protection offered by the CoC. 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.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website 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.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA), and/or other government officials 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.

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.

This trial may be registered on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), a publicly available registry of clinical trials.

### 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

### 9.4 When does my permission expire?

Your permission will not expire unless you cancel it.

## 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  
University of Michigan  
Department of Psychiatry  
2800 Plymouth Road, NCRC, Building 16  
Ann Arbor, MI 48109-2800

**Telephone:** 734-615-4225

**Study Coordinator:**

Diane Schneeberger, LMSW  
University of Michigan  
Department of Psychiatry  
2800 Plymouth Road, NCRC, Building 16  
Ann Arbor, MI 48109-2800

**Telephone:** 734-615-4479

Or visit our website at [www.ProjectAmaze.org](http://www.ProjectAmaze.org)

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 (For International Studies: US Country Code: 001)

Fax: 734-763-1234

e-mail: [irbmed@umich.edu](mailto: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 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.)*

[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 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.

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 Project Amaze research study?

**YES** – I have read and understand the information above. I am between the age of 16 and 24 years old, and 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.



submit button