IRB-Approved Consent Forms for:

Text Message Intervention for Alcohol Use and Sexual Violence in College Students

NCT05065918

October 12, 2021

CONSENT FOR RESEARCH
The Pennsylvania State University

Title of Project: *Student Perspectives on a Text Message-Delivered Intervention to Address Campus Sexual Violence and Alcohol Use - Phase 2*

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- We are asking you to be in a research study.
- This document gives you information about the research.
- Whether or not you take part is up to you. **You can choose not to take part.**
- You can agree to take part and later change your mind and your decision will not be held against you.
- **Please ask questions about anything that is unclear to you and take your time to make your choice.**

1. **Why is this research study being done?**
   The purpose of this voluntary research study is to collect formative feedback from college students regarding their opinions for a proposed text message intervention to address sexual violence and alcohol use. Approximately 250 college students will take part in this research study.

2. **What will happen in this research study?**
   In this research study, participants will:
   - Be asked to complete three surveys, one survey at the start of the study, one 3 months later, and one 6 months later.
   - Receive one or two different sets of text messages about alcohol safety or alcohol and sexual violence safety for 3 months, some messages may ask you to respond and provide information about your alcohol use or sexual violence safety
   - Which set of text messages you receive will be randomly assigned by a computer. Randomly assigned is like flipping a coin or rolling dice – after you decide to join the study the computer will decide which set of messages you will get.
   - You may be asked to participate in an interview after receiving the 3 months of text messages

3. **What are the risks and possible discomforts from being in this research study?**
   Some risks are potential loss of confidentiality, and that some of the questions asked or information in the text messages may be distressing for you based on your past experiences or knowledge. Based on what we know from prior research, the likelihood of these risks causing serious discomfort or inconvenience is low. You can check out our resources page at any time (whether you sign up for the study or not) if you are just interested in resources and information).
   There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the study team, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the study team will be maintained as required by all applicable law and to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

4. **What are the possible benefits from being in this research study?**
   There may be no direct benefit to you from participating in the study. It is possible that some of the survey questions or text messages may prompt self-reflection, help you change behaviors, or introduce you to resources that you were unaware of – we cannot guarantee this.
   4b. What are the possible benefits to others?
   The results of this research may provide important information that is may us address the issues of sexual violence and alcohol use in young adults in the future.

5. **What other options are available instead of being in this research study?**
   Participation in research is your choice. If you decide not to participate, you will not have access to the study surveys or text messages. We can still provide you with our community resources list if you are interested in other resources about sexual violence and alcohol.

6. **How long will you take part in this research study?**
   The study will last approximately 3 months from the time you sign up. You will receive an online survey at the beginning of the 3 months and one at the end, both taking approximately 15-30 minutes. Text messages will be sent between the first and last survey, and you will be asked to respond to the text messages during that time. It should take no more than one-two minutes to respond to those text messages each week. You may be asked to participate

in an interview after 3 months of text messages. The interview is expected to last approximately 1 hour, and can be conducted virtually via Zoom conference, or on the University Park campus.

7. How will your privacy and confidentiality be protected if you decide to take part in this research study?

7a. What happens to the information collected for the research?

Efforts will be made to limit the use and sharing of your personal research information to people who have a need to review this information. Reasonable efforts will be made to keep the personal information in your research record private. However, absolute confidentiality cannot be guaranteed.

- For electronic data, only authorized users will have access to the database where data is stored. Study data is stored using appropriate passwords and data encryption. Your identifying information (name, phone number, etc) is stored separately in the database than your answers to survey questions.
- For interview audio files, they will also be stored without identifying information and will be deleted after they are transcribed and checked for accuracy. Only written de-identified transcripts will be maintained as part of the ongoing study record.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot disclose information that identifies you to anyone not connected with the research. This protection also prevents this information from being used or disclosed for legal proceedings, such as being accessed through a court order. The Certificate of Confidentiality however does not prevent disclosures required by law, such as information about child abuse and harm to yourself or others. Also, your information may be disclosed in accordance with any consent you provide, including for your medical treatment or use in other research. Additionally, the Certificate of Confidentiality does not prevent your information from being disclosed to the National Institutes of Health for them to evaluate or audit the research, or prevent disclosures required to meet FDA requirements. For additional information ask the principal investigator or a member of the study team or contact the Office for Research Protections at (814) 865-1775.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

We will do our best to keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people may find out about your participation in this research study. For example, the following people/groups may check and copy records about this research.

- The Office for Human Research Protections in the U. S. Department of Health and Human Services
- The research study sponsor, the National Institute on Alcohol Abuse and Alcoholism
- The Institutional Review Board (a committee that reviews and approves research studies) and Penn State's Office for Research Protections.

7b. What will happen to my research information after the study is completed?

We may use your research information for future research studies or may share your information with other researchers here or at other institutions for future research without your additional informed consent. Future research may be similar to this study or completely different. Before we share your information we will remove any information that shows your identity.

8. What are the costs of taking part in this research study?

There is no specific cost for participants in this study

8a. What will you have to pay for if you take part in this research study?

You need to have a cell phone with an unlimited text message plan and internet access, so that you are not being charged for receiving messages.

9. Will you be paid or receive credit to take part in this research study?

You will receive prepaid Amazon.com gift cards for your participation. You will receive**:**

- $20 for completing the baseline survey
- $30 for completing the 3 month survey
- $50 for completing the 6 month survey
- $20 for completing the interview (if selected)

10. Who is paying for this research study?

The institution and investigators are receiving a grant from the National Institute on Alcohol Abuse and Alcoholism (NIAAA) to support this research. The sponsor NIAAA is paying Penn State to allow this research to be done.

11. What are your rights if you take part in this research study?

Taking part in this research study is voluntary.

- **You do not have to be in this research.**
- If you choose to be in this research, you have the **right to stop at any time.**
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

We may remove you from the research study without your approval. Possible reasons for removal include enrolling in the study, but not completing the first survey.

If new information is learned about how the text messages work or other information we think may impact your decision to participate, we will share it with you.

12. If you have questions or concerns about this research study, whom should you call?

Please call the head of the research study, Jocelyn Anderson, at 814-867-5999 or jcandresearch@psu.edu if you:

- Have questions, complaints, or concerns about the research..

You may also contact the Office for Research Protections at (814) 865-1775, IRB-ORP@psu.edu if you:

- Have questions regarding your rights as a person in a research study.
- Have concerns, complaints, or general questions about the research.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

You may visit the Office for Research Protections' website at https://www.research.psu.edu/irb/participants for:

- Information about your rights when you are in a research study;
- Information about the Institutional Review Board (IRB), a group of people who review the research to protect your rights; and
- Links to the federal regulations and information about the protection of people who are in research studies. If you do not have access to the internet, copies of these federal regulations are available by calling the ORP at (814) 865-1775.

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.