

Text-based Alcohol Prevention for First Year College Students

NCT03864237

Consent Form

Final version 8/6/18

BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION
FACT22 Study
Version 10, 8/06/2018

You are invited to take part in a Brown University research study. Your participation is voluntary.

- **RESEARCHER:** Dr. Kate Carey (kate_carey@brown.edu) is the principal investigator of this study.
- **PURPOSE:** This study seeks to deliver and gather feedback about information that may be shared with students as they adapt to college life, delivered via text messaging. You are being asked to be in this study because you are a first-year student attending Brown University.
- **PROCEDURES:** (1) After reading this form, if you agree to participate, you will be asked to provide contact information so that we can send you an online baseline survey (this should arrive within two days). This survey will ask basic questions about you (e.g., your age, gender) and your social and health beliefs and behaviors (e.g., stress levels; alcohol, drug and tobacco use; mental health; sexual activity; and sleep habits). (2) After completing the confidential survey, you will sign up to come in for a brief group orientation meeting to learn more about the next steps in the study. (3) Next, participants will be randomly selected to receive and provide feedback ratings on one of two sets of text messages, delivered once per day for 10 weeks. Some participants will receive text messages that accurately describe the drinking behaviors of other students on campus, and others will receive messages about interesting historical events. (4) At the end of the 10 weeks (in December), you will be invited to complete an online follow-up questionnaire. (5) Again 3 months later (in March), you will be invited to complete another online questionnaire; at that time, you will complete the study.

With respect to receiving and rating the text messages, it is important for you to know:

1. We will send text messages between the hours of 4-8pm.
2. It will take less than one minute to respond to each message. We will ask that you respond to each message (with a single numerical rating) in a private location as soon as possible after you receive it. If you are in class or driving, please wait to respond at a later time.
3. Your ratings are confidential.
4. We will keep a record of your responses to all messages.
5. In total, you will send 70 messages, and receive ~140 text messages (one fact per day plus one autoreply to your rating of that fact), which will require the use of cellular data. Standard charges per your own data plan will apply.
6. We will not be able to respond in real-time to your text messages; we will simply receive your responses to the questions we send (asking for a rating of each message). If you are experiencing an emergency, you should call 911.
7. You can opt out of receiving text messages at any time by texting STOP.

- **TIME INVOLVED:** From start to finish, you will be enrolled in this study for approximately 6 months. During this time, you will be asked to (1) complete a 45-minute baseline questionnaire, (2) attend a 20-minute orientation meeting, (3) respond to one daily text message for 10 weeks (taking <1 minute each day), and (4) complete two additional 45-minute online surveys, one at the end of the 10 weeks of messages and one 3 months later.

- **COMPENSATION:** You can receive up to \$140 for participating in this study. You will receive \$25 for completing the baseline questionnaire and attending the orientation, \$30 for completing a follow-up survey at the end of ten weeks, and \$35 for completing another follow-up survey after 3 months. Note that providing ratings of the texts are incentivized as follows: All participants who rate at least 90% of the daily text messages will be entered to win one of four \$50 bonus payments, to be raffled off at the end of the 10 weeks; your odds of winning will be at least 1 in 30.

Payment for participating in this study will be made using ClinCard, a pre-paid Mastercard that works like a debit card. We will give you the debit card during your orientation. You will have one card for the duration of this study and this card may be used to pay you in any future Brown University studies you choose to participate in. You will also receive information about how to use this card and whom to call if you have any questions. Be sure to read this information, including the cardholder agreement from Greenphire.

Money will be added to your card according to the study's payment schedule. You may use this card online or at any place that accepts Mastercard. Please read the FAQ information sheet from your study coordinator for details about the ways you can use the card, some of which may involve fees that will reduce the amount of money on the card.

If you earn \$600 or more from Brown University in a single calendar year (either in a one study or across multiple studies), Brown will ask for your social security number to correctly identify you in the payment system and send you an IRS 1099 Form. You may also be asked to complete a Form W9. This may affect your taxes. Only payments for being in research studies will be used to decide if you should receive the IRS form. Money for study-related parking, food, and other expenses are not included in this IRS disclosure.

This card is administered by an outside company called Greenphire. Greenphire will be given your name, address, and date of birth. They will use this information only as part of the payment system and *it will not be given or sold to any other company*. Greenphire will not receive any information about your health status or the study in which you are participating. If your card is lost or stolen, please email us at fact22@brown.edu for a replacement card. If you request a replacement card from Greenphire directly, you may be charged a fee.

- **RISKS:** The risks in this study are minimal. The surveys ask about your social and health behaviors and related beliefs and attitudes. The daily questions about the text messages ask only for a rating of your level of interest in that information. It is possible that answering questions in this study might cause some discomfort. You do not have to answer any question that you do not feel comfortable answering. You may withdraw from the study at any time without penalty. In the event that participation in this study triggers the desire to further discuss your health behaviors or other issues with a professional, you may obtain confidential help at the Brown Counseling and Psychological Services Center. A referral list containing contact information for this and other student resources will be provided to all participants in this study.
- **BENEFITS:** We cannot and do not guarantee or promise that you will receive any direct benefits from this study. However, you will be contributing to research that may lead to better programs for future college students at Brown and elsewhere.
- **CONFIDENTIALITY:** Participation in this study and information gathered from the study will be kept confidential. We will not connect your name to any research data. Instead, we will assign

a code number to your information. We will keep the master list that links your name to your code number separate from your questionnaire responses. All text messages sent and received will be stored on a secure server accessible only to Brown project staff. We recommend that you password protect your mobile phone and respond to study text messages in private.

This research is covered by 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) without your consent. 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 any person not connected with the research, you must provide consent to allow the researchers to release it.

There are a few exceptions to confidentiality protections. Because this study is regulated by the Brown University Institutional Review Board (IRB), the IRB may choose to inspect research records that identify you. Also, we cannot refuse a request from United States Government personnel for information that is needed for auditing or evaluation of federally funded projects. Lastly, the Certificate of Confidentiality does not prevent us from disclosing to state or local authorities if you reveal any intention to hurt yourself or anyone else, or child and elder abuse.

- **VOLUNTARY:** You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time. There will be no penalty if you decide not to be in the project or withdraw from the project later.
- **CONTACT INFORMATION:** If you have any questions about your participation in this study, you can contact Dr. Kate Carey at kate_carey@brown.edu or (401) 863-6558. Research staff can be contacted by email at fact22@brown.edu.
- **YOUR RIGHTS:** If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu.
- **CONSENT TO PARTICIPATE:** Clicking on "Yes, I agree to participate in this study" confirms that you have read and understood the information in this document, are at least 18 years of age and that you agree to volunteer as a research participant for this study.

Yes, I agree to participate in this study
 No, I do not want to be in this study

You may download a copy of this form for your records.

[\[Link for PDF of Consent form\]](#)