Research Consent and Authorization Form

Rhode Island Hospital, The Miriam Hospital, EP Bradley Hospital, Newport Hospital, and Gateway HealthCare

Name of Study Participant: _____

Principal Investigator: Beth Bock PhD

Title of Research Study: C.A.R.E.S.: A Mobile Health Program for Alcohol Risk Reduction

Study Key Information

You are being asked to take part in a research study. A research study helps scientists learn new information to improve human health. This form contains information that will help you decide whether to take part in the research. Taking part in this study is completely voluntary. Even if you decide to take part in the study, you are free to leave at any time if you change your mind. The researcher will explain the study to you and answer any questions you may have. We encourage you to discuss this study with others (your family, friends, or doctors) before you agree to participate in the research. If you agree that you would like to participate in this research study, you will be asked to review and sign this consent. A copy will be given to you.

A. What is the purpose of the research?

The purpose of this study is to learn more about how a new smartphone app-based program (CARES), designed to provide help and advice, helps to reduce the risks of drinking among community college students.

B. What is experimental/new in this study

To see if the CARES App helps reduce the risks associated with drinking among community college students, you will be assigned randomly (like a coin toss) to a group that either receives to the CARES App (Group A) or an alternative alcohol education program (Group B).

C. What do I have to do in this research?

Participants will be asked to use the CARES app for 12 weeks or access a website with an alternative alcohol education program. You will also be asked to complete a survey today and again at weeks 4, 8, 12, and 26. At 12 weeks, you may also be invited to participate in a short interview about your experiences in the study.

Lifespan - The Miriam Hospital IRB
IRBNet ID: 1231146-22
Approved: December 28, 2020
Expiration: December 27, 2021
Does not expire if expiration date is blank

D. What could go wrong?

The most important potential risks of this study are: (1) loss of confidentiality of information you shared via the surveys; (2) emotional discomfort responding to questions about your alcohol use.

E. What are the benefits?

You may benefit by learning more about alcohol safety. There are no other direct benefits to you of taking part in this research. Others may benefit in the future from the information that is learned in this study.

F. Other things I should know about this research?

If we learn information from this research that may affect your health, safety, or willingness to stay in this research, we will contact you immediately.

G. If I don't want to take part in this research what are my other choices?

You do not need to be in the study to learn about alcohol safety.
If you want help or to discuss your alcohol use with someone, here is a list of counseling and other services:

- SAMHSA's National Helpline, 1-800-662-HELP (4357) is a confidential, free, 24-hour-a-day, 365-day-a-year, information service, in English and Spanish, for individuals and family members facing mental and/or substance use disorders.
- Butler Hospital, Providence RI, 1-844-401- 0111.
- The Providence Center, RI: https://providencecenter.org/services/adult-services/outpatient-treatment

- **Please carefully read and review this form, additional detail about each item above is found below.**
- **Please ask questions about anything that is not clear.**

1. Nature and Purpose of the Study

You are being asked to take part in a research study because you are a currently enrolled community college student between ages 18 and 29, drink alcoholic beverages, own a smartphone, and use apps on your smartphone. In this study we are comparing a new smartphone app designed to provide help and advice to reduce risks of drinking compared to an online alcohol education program. We plan to enroll a total of 250 participants into this study. This study is sponsored by the National Institute on Alcohol Abuse and Alcoholism (NIAAA), which is part of the National Institutes of Health (NIH).

2. Explanation of Procedures:

You will be randomly assigned, "randomized", into one of the study groups that receives either the CARES App (Group A) or an alternative alcohol education program (Group B). Randomization means that you are put into a group by chance. It is like flipping a coin. Which group you are put in is done by a computer. Neither you nor the researcher can choose what group you will be in. You will have an equal chance of being placed in any group.

Regardless of which group you are in you will be asked to participate in the study for 6-months. Participants will complete study surveys at baseline (today) 4-, 8-, 12-, and 26-weeks. At 12 weeks you may be invited to participate in a interview about your experiences in the study. We will be interviewing 20-24 CARES participants. These interviews will be conducted either in person or over the phone and will last 30-45 minutes. Not everyone will be selected to participate in this interview. Interviews will be audio-recorded and then a detailed audio review and interview summary will be written for each interview. These summaries will not contain any information that could identify you. To protect your privacy, audio-recordings will be destroyed upon study completion. Your identifiable private information that has been collected as part of the research will not be used or shared with other researchers for future research studies.

This study involves using a smartphone application (CARES App) as part of this research study. This may include you receiving and sending information via the CARES App. Lifespan takes your confidentiality seriously and will take steps to protect the information contained in the app to the degree permitted by the technology being used. Depending on the nature of the study, some of the following steps may be taken: encrypting the data during transmission, storing all data gathered on secure servers, providing you with a secure device when the circumstances warrant, and/or remote data deletion in the event of a lost or stolen device. The CARES App is hosted by Amazon Web Services (AWS). The AWS is used to create a Health Insurance Portability and Accountability Act (HIPAA) compliant application—the CARES app—to process, store, and transmit data. Our web configuration interface is protected with an encrypted, user-generated username password combination, following standards of the industry. Data stored on the phone is minimal and protected by the phone's security.

However, Lifespan can make no guarantees about the secure transmission of information you send to us, nor can Lifespan guarantee security after you receive any message from Lifespan.

For example, messages that display on your phone screen may be seen by someone close by or by someone you have allowed to use your phone. Also, if you do not password protect your phone and it is lost or stolen, anyone who finds it might view the information in the messages about your health or other topics. To try to lessen these risks, you should make sure your phone is password protected, only open and view messages where no one will be able to view the screen and delete messages as soon as possible after reading them. Additionally, when you trade in your phone, remember the SIM card (memory card used in cell phones) should be cleared.

Finally, it is also possible that the mobile phone company that transmits the messages may keep copies of ALL your messages (those from the study, and your other apps or text messages) even after the study is ended. Lifespan has no control over these companies and cannot make any guarantees about their conduct.

Compensation: You will receive an Amazon eGift Card emailed to you for your time and effort each time you complete the following study surveys. You will receive a $25 Amazon eGift Card for completing your baseline survey, and a $15 Amazon eGift Card for each of the two brief surveys completed at week 4 and week 8. You will also receive a $50 Amazon eGift Card for completing your 12-week and 26-week follow-up surveys. If you are selected for an interview at 12 weeks, you will be compensated $50 for your time upon completing the interview. Therefore, you may be compensated up to $205 for your time and effort for the completion of the surveys.

Costs for participating in this study: While there are no direct costs to you for participating in this study, standard data and text messaging fees will apply based on your mobile data and text messaging plans with your mobile phone carrier. You will **NOT** be reimbursed for these charges. Please review your data and text messaging plans prior to enrolling in the study

Contact Information:
If you have any questions about this study, please contact the study Principal Investigator, Beth Bock, PhD, at 401-793-8020.

3. Discomforts and Risks

The risks in this study are considered minimal with the primary risk being loss of confidentiality of information shared via the surveys or materials provided to researchers as described above. You may experience some emotional discomfort responding to questions about your alcohol use, but we do not consider this potential risk to be either common or serious. You may refuse to answer any question you do not feel comfortable answering.

If you are under age 21 the survey questions you answer may contain information about your alcohol drinking which is illegal in the state of Rhode Island and Massachusetts. The information you provide is protected by a Certificate of Confidentiality (CoC) the study received from the U.S. Department of Health and Human Services – Office of Human Subjects Protections. The CoC protects the privacy of research participants by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the

participant consents or in a few other specific situations (for example, when required by law, for example disclosing child abuse, or when needed for medical treatment).

4. Benefits

You may benefit by learning more about alcohol safety. You will not receive any other direct benefit from your participation in this study. We hope that the information provided in this study may help future community college students reduce the risks associated with their drinking.

5. Alternative Therapies

You do not have to participate in this study to change your drinking behavior. If you want help or to discuss your alcohol use with someone, here is a list of counseling and other services:

- SAMHSA's National Helpline, 1-800-662-HELP (4357) is a confidential, free, 24-hour-a-day, 365-day-a-year, information service, in English and Spanish, for individuals and family members facing mental and/or substance use disorders.
- Butler Hospital, Providence RI, 1-844-401- 0111.
- The Providence Center, RI: https://providencecenter.org/services/adult-services/outpatient-treatment

6. Refusal/Withdrawal

It is up to you whether you want to be in the study. You are not required to enroll or participate. If you decide to participate, you can always change your mind and quit at any time. If you decide not to be in the study, or if you quit later, you will still be able to get the health care services you normally get. If you join, but later the researcher or your doctor feels being in the study is no longer good for you, they may choose to take you out of the study before it is over. If new information becomes available that might change your mind about whether you want to stay in the study, the researcher will share this information with you as soon as possible.

Reasons the researchers would take you out of the study even if you wanted to stay in:

- 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.

7. Medical Treatment/Payment in Case of Injury

This study does not include any treatment or intervention; therefore, a research related injury/illness is unlikely to occur.

8. Rights and Complaints

Signing this form does not take away any of your lawful rights. If you have any complaints about this study or would like more facts about the rules for research studies, or the rights of people who take part in research studies, you may contact Janice Muratori in the Lifespan Office of Research Administration, at (401) 444-6246.

9. Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information.

Your research records will be treated as private health care records and will be protected according to Lifespan privacy practices and policies that are based on state and federal law. Federal law requires us to get your permission to use or disclose (release your information to someone outside of Lifespan) your health information for research purposes. If you respond "Yes—I consent to participant in this study" at the end of this informed consent form, you agree to be in this research study and you permit the use and disclosure of your health information for the purpose of conducting the research, providing treatment, collecting payment and running the business of the hospital. This permission has no expiration date. You may withdraw from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study, you must cancel permission in writing and may do so at any time. If you cancel your permission, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you by the hospital or the researchers before you canceled your permission.

Generally, the entire research record may be used for research purposes. The following people or businesses/companies might use, release, or receive such information:

- The researcher and their support staff;
- The study sponsor NIH-NIAAA and Live Inspired
- Doctors, nurses, laboratories and others who provide services to you or the sponsor regarding this study;
- The company or section of the U.S. government that is paying for the study and others they hire to oversee, administer, or conduct the research;
- The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, the Office of Civil Rights, European Medicines Agency
- People who volunteer to be patient advocates or research volunteer protectors;
- Members of the hospital's administrative staff responsible for reviewing, approving and administering clinical trials and other healthcare or research activities.
- Accrediting Organizations

There are times when the law might require or permit Lifespan to release your health information without your permission. For example, Rhode Island law requires researchers and health care workers to report abuse or neglect of children to the Department of Children, Youth

and Families (DCYF) and to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

All researchers and health care providers are required to protect the privacy of your health care information. Other people and businesses/organizations that are not health care providers are not required by law to do that, so it is possible they might re-release your information.
You have the right to refuse to sign this form and not participate in the research. Your refusal would have no effect on your treatment, charges billed to you, or benefits at any Lifespan health care site. If you do not sign, you will not be able to enroll in the research study and will not receive treatment as a study participant.

If you decide to quit the study after signing this form (as described in Section 6: Refusal/Withdrawal), no new information will be collected about you unless you gave us permission to do so. However, the hospital or the researchers may continue to use information that was collected before you quit the study to complete analysis and reports of this research. You will not be allowed to see or copy the information described in this form if the research is open. You may see and copy the information when the study is completed.

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.

The National Institutes of Health has issued a Certificate of Confidentiality for this research. This adds special protection for the research information and specimens that may identify you. The researchers may not disclose information that may identify you, even under a court order or subpoena, unless you give permission. However, a Certificate of Confidentiality does not prevent researchers from disclosing information about you if required by law (such as to report child abuse, communicable diseases or harm to self or others); if you have consented to the disclosure (such as for your medical treatment); or if it is used for other research as allowed by law. In addition, the Certificate cannot be used to refuse a request if a governmental agency sponsoring the project wants to audit the research. Any research information that is placed in your medical record would not be covered under this Certificate. The Certificate will not be used to prevent disclosure for any purpose you have consented to in this informed consent document. The Certificate does not stop you from voluntarily releasing information about yourself or your involvement in this research. If others obtain your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Before you decide if you want to participate in the CARES Study, we want to make sure you fully understood the information provided in the informed consent document so you know what you are will be asked to do if you decide to participate.

Please answer the following questions about the information you just read from the informed consent document.

If you respond incorrectly to a question, the correct response will be provided to you:

1. **People who join this research study will be assigned randomly to one of 2 groups?**
   - € True
   - € False

[If participant selects "false", the correct information will be provided:
Actually, this is true. You will be assigned randomly (like a coin toss) to a group that will be given access the CARES App (Group A) or will be given access to an online alcohol education intervention Check Your Drinking (Group B).

2. **Information that can be used to identify me, for example, my name, address, phone number, and email address, will be kept confidential and will be destroyed at the end of the study.**
   - € True
   - € False

[If participant selects "false", the correct information will be provided:
This is true. All information identifying you will be kept confidential and destroyed at the end of the study.]

3. **I can quit the study anytime by calling or emailing the researchers.**
   - € True
   - € False

[If participant selects "true", the following additional information will be provided:
It is true that you can quit the study at anytime by simply calling or emailing the researchers. However, if you wish to withdraw permission for us to use already collected data, you must do that in writing.]

[If participant selects "false", the correct information will be provided:
This is true. You decide whether you want to be in the study. Participation is voluntary. If you decide to participate, you can change your mind later and quit the study at any time. However, if you wish to withdraw permission for us to use already collected data, you must do that in writing.]

ELECTRONIC SIGNATURE

I have read this informed consent and authorization form. ALL MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.

- € **YES – I consent to participant in this study**
- € **NO – I do not consent to participate in this study**

[If participant selection "no", they will be asked why they decided not to participate:

Thank you for taking the time to complete our eligibility screener and for reading over the consent form. We would like to learn why you do not wish to participate in this study. Please enter your reason in the box below. This will help us in developing programs in the future.]

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[If participant selects "yes", they will be asked to provide their school email address as shown below.]

Please Enter Your Full Name Here:

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As part of the eConsent and Verification Process, Please Provide your School Email Address:

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(Note: You must provide your school email address. We will email you a copy of the informed consent form to the school email address provided here.)

Date and Time:

_____