

bhoos Consent Fall 2022

Informed Consent Agreement.

Please read this consent agreement carefully before you decide to participate in the study.

Consent Form Key Information: You are being invited to participate in a research study titled “Pilot-testing Updates to the bhoos App for College Binge Drinking” (IRB-SBS #5334). You were selected to participate in this study because you are a University of Virginia student. This study is being done by investigators at the University of Virginia.

Background: Drinking has been a part of the University of Virginia student culture. At times, students have been hurt and even died because of their own or others’ heavy drinking. We conducted formative research with current students, faculty, and staff to understand their views on the problem, the impact of current efforts at alcohol education, and the acceptability of potential interventions. We took what we learned along with other research and built the bhoos (pronounced “booze”) app as a tool to help students be safer when drinking.

During this study, you will: Take 2 surveys, one at the beginning and one at the end of a month; Download and use an app for 30 days; Participate in up to 2 focus groups or one-on-one interviews about your experiences using the app. The app is designed to help students at the University of Virginia be safer while using alcohol or being around people drinking. Your study information will be kept confidential, and the information you provide is protected by a Certificate of Confidentiality from the National Institutes of Health.

Purpose of the research study: The purpose of this research study is to test the usefulness, usability, and acceptability of the bhoos mobile app for UVA students. You are being asked to be in this study because we need to test the app with students in the real world and want to hear what you think. Some of our research questions include: Is the bhoos app easy to use? Does the app help you? Does the app work consistently? Your experiences and ideas are extremely valuable to us, and by testing the app for us, you will help us refine the app and further develop the program for future UVA students.

What you will do in the study: You will be provided with information about the study so you can decide if you want to participate. If you consent to participate in the study, you will first complete an online baseline questionnaire, which is a survey that will take about 30 minutes to complete on average. It will ask about your characteristics and interests as a student, along with some questions about your attitudes, moods, and drinking behaviors. You will have up to 72 hours to complete the baseline questionnaire. If you don’t complete it in one

sitting, you will get up to 3 reminders sent to your email. If you don't submit it within 72 hours, you will be dropped from the study and if you want to rejoin, you will have to start over with a new interest form.

Once your baseline questionnaire is submitted, you will be sent an email with a unique access code that will allow you to download the bhoos app, and use it for a period of 30 days.

At the end of the 30 days, you will be sent an email asking you to complete a second, online final questionnaire. The final questionnaire will be longer than the baseline and will take about 45 minutes to complete. You will be asked about yourself, your mood, drinking, and your opinions of the bhoos app. You will also provide your opinion and experiences with specific features and functions of the bhoos app.

About two weeks after you download the app, you may be contacted to participate in a focus group with other test users or a one-on-one interview about your experiences using the app. After the trial period is up and you have completed the survey, we may again reach out to ask you to participate in a focus group or one-on-one interview.

At the end of the study, you will receive compensation for each activity you complete. The total compensation you will receive for your time in completing the baseline questionnaire, focus groups/interviews, and final questionnaire in this study will be \$75 in gift cards.

You may not directly benefit from this research; however, we hope that your participation in the study may help others in the future. The purpose is to help us understand the usability of the app and to see if it has an impact on drinking behaviors.

Time required: The study will require less than an hour of your time for each survey and 20 minutes to download and install the app. The amount of time that you use the app over the next 30 days is up to you. You will need to complete the baseline survey before you download and install the app, and the follow-up survey will be sent to you approximately 30 days after you submit the baseline survey. Each focus group or interview will last no more than 90 minutes.

Risks: There are a few risks associated with this study. The primary one is related to an important feature on the app. This feature allows you to "log" or track a drink, which may be alcoholic or a dry day. Those who track their alcoholic drinks in real time will see displays of their estimated blood alcohol concentration (eBAC). THE eBAC number is intended to help you to be safer when making choices about behaviors such as drinking and driving, interacting with others, continuing to drink and more. The risk is that some participants may

share their estimated BAC and this might lead to a competition for higher alcohol concentrations. We recommend against use of the bhoos app as a “drinking game,” because it increases the risks of dangerous drinking behaviors. To reduce this risk, we provide context and guidance within messages that are automatically sent to all users based on timing or specific events, and within the Emergency and Safety “topics” featured in the app. We ask you to keep your BAC estimate private. You should be aware of this potential risk and avoid sharing your eBAC information to keep yourself and other UVA students safe. Some of the questions asked in the surveys or focus groups may be upsetting, or you may feel uncomfortable answering them. Some of the questions asked may make you angry, emotionally upset, or stressed out now or at a later time. If this happens, please contact the study team, or use one of the contacts for help provided. Remember, **you do not have to answer any question you do not want to or that makes you uncomfortable.**

There is a risk of breach of confidentiality. This risk is unlikely but should this occur would be minimally serious due to the type of information we will be collecting. To minimize this risk: **a.** Notes from your focus group session will be kept separate from the participant list and signed consent forms. Notes will be kept on a secure server and will be accessible only to the research team. **b.** We ask you to keep in mind that if you admit to underage drinking and there is a breach of confidentiality, there is a remote possibility that you could be identified. Consider describing things you have seen, not done.

Please only use first names when addressing another member of the group, and refer to groups in general terms (eg, “My fraternity” not “Kappa Alpha”). The other potential risk to you is a breach of your privacy. There are no known data security risks associated with participating in this research study; however, the risk of a breach of privacy is always possible. To the best of our ability your answers in this study will remain confidential. We will minimize risks by not recording your name or other specific identifiers in relation to your answers.

Some people may become concerned about their alcohol use after completing the questionnaires or using the app. As researchers, we will not be following up with you about your drinking after this study. If you feel upset at any point while participating in the study, or find that some questions or aspects of the study triggered distress, talking with a qualified clinician may help.

If you would like assistance, please contact the Substance Use Disorder Treatment and Consultation Team (<https://www.studenthealth.virginia.edu/substance-use-disorder>) at Student Health at 434-924-5362 (after hours: 434-297-4261). In the case of an emergency please call 911.

Risks of Videotaping/Audio taping: You will be audiotaped as part of this study if you

participate in a focus group or interview. We do this because we don't want to miss anything you might say. Only first names will be used. If a full name (or distinctive first name) is used, it will be redacted from any transcripts. The audio recordings will be stored on an encrypted, token-protected, secured server, and will be destroyed at the end of the study. If you decide you no longer want to participate, we will stop the recording until you have left the room.

Benefits: You may not directly benefit from this research; however, we hope that your participation in the study may help others in the future. The purpose is to help us understand the usability of the app and to see if it has an impact on drinking behaviors. It may also make you aware of your own drinking patterns, and give you the opportunity to learn new information about how to drink responsibly.

Confidentiality: This study is confidential. Your data will be stored on secured servers using a unique study ID. During the study, we will use your email to contact you, but after the study, we will delete your email. At that point, your data will only be coded with the unique study ID which will not have any association to you. We will not have any identifying information on you and there will be no way to associate your responses to you. It is rare for researchers to be asked to release any study data except for routine review by IRB monitors.

Certificate of Confidentiality: This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena. There are some important things that you need to know. **The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.** The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations. Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information. In simple terms, the Certificate of Confidentiality means that we will not disclose your individual alcohol use information to the University, the police, or other officials. However, the members of the research team also have an ethical obligation to report any serious concerns to authorities that you will do harm to yourself to others and will voluntarily do so if needed to protect you

or others. Note, this has not happened in our previous research on the bhoos app.

Voluntary participation: Your participation in this study is completely voluntary and you can withdraw at any time. On the questionnaires, you may decline to respond to any question that you don't want to answer. **Right to withdraw from the study:** You have the right to withdraw from the study at any time without penalty, and your participation or decision to not participate will not impact your standing as a student at the university in any manner. **How to withdraw from the study:** If you decide to withdraw from the study during your active period (the 30 days we ask you to have the app installed on your phone and while you complete the final survey), please contact the study team at bhoosstudy@virginia.edu. Please give us your @virginia.edu email address and state that you are withdrawing from the study. We would appreciate a reason for why you choose to withdraw but it is not required. You will then delete the app from your smart phone. If you choose to withdraw after your active participation is complete, please email bhoosstudy@virginia.edu. If your data has already been made anonymous, we will not be able to delete your information from the study. If it has not been through this process, we will delete your study data.

There is no penalty for withdrawing and withdrawing will not affect your experience as a student. Withdrawing will not affect your grades or school services. You will still receive payment for the portions of the study you complete.

Payment: You will receive payment for participating in the study if you complete the surveys and the focus groups/interviews. Payments will be made at the end your study participation via Tango, a website that allows you to choose gift certificates that match your interests, including more than 100 stores including Amazon, DoorDash, GameStop, and Kroger. The total compensation you will receive for your time in completing the baseline questionnaire and final questionnaire in this study, as well as participating in the two focus group or interview sessions, will be up to \$75 in gift cards.

Using data beyond this study: We will use the information and data from this study to inform our development of a larger trial of the bhoos app among University of Virginia students. Your anonymous responses and user data will allow us to know what features work best among UVA students and what areas we need to improve before introducing it to a larger group of users.

The researcher would like to make the information collected in this study available to other researchers after the study is completed. The researcher will remove any identifying information (such as your name, contact information, etc.) connected to the information you provide. The researcher will share all of the information collected in this study (not just your individual file) with other researchers for future research studies, including but not limited to drinking behaviors among university students. The researcher will make the information

available on a public database. Researchers of future studies will not ask your permission for each new study. The other researcher will not have access to your name and other information that could potentially identify you nor will they attempt to identify you.

If you have questions about the study, contact:

Karen Ingersoll, PhD.

Department of Psychiatry and NB Sciences,

560 Ray C. Hunt Dr.

University of Virginia,

Charlottesville, VA 22903.

Telephone: (434) 982-5960

Email address: KES7A@hscmail.mcc.virginia.edu

To obtain more information about the study, ask questions about the research procedures, express concerns about your participation, or report illness, injury or other problems, please contact:

Tonya R. Moon, Ph.D.

Chair, Institutional Review Board for the Social and Behavioral Sciences

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University of Virginia, P.O. Box 800392

Charlottesville, VA 22908-0392

Telephone: (434) 924-5999

Email: irbsbshelp@virginia.edu

Website: <https://research.virginia.edu/irb-sbs>

Website for Research Participants: <https://research.virginia.edu/research-participants>

UVA IRB-SBS #5334

Agreement: I agree to participate in the research study described above

SIGN HERE

clear

Please type your name

Today's date

You will receive a copy of this form via email for your records.

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