UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

GENERAL INFORMATION ABOUT THIS STUDY

1. **Name of Participant ("Study Subject")**

   _____

2. **What is the Title of this research study (this "Research Study")?**

   A Smartphone App to Capture Inhibitory Control as a Novel Moderate Drinking Tool

3. **Whom do you call if you have questions about this Research Study (the "Study Team")?**

   Principal Investigator: Liana Hone, Ph.D., FLG Room 126, 352-294-1801
   Study Physician: Robert Cook, M.D., MPH, 9923 SW 2nd Place, 352-275-9930 (number to call for 24-hour assistance)

4. **Who is paying for this Research Study?**

   The sponsor of this study is National Institute of Alcohol Abuse and Alcoholism

   (NIAAA)

5. **In general, what do you need to know about this Research Study?**
   Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) In general, what is the purpose of the research, how long will you be involved?

The purpose of the study is to test an alcohol-related smartphone application designed to provide assistance during actual drinking situations to help young adults reduce their drinking. You will play a cognitive game through the app. Afterward you may receive feedback about how you performed on the game and will then answer a short series of questions. You may also have the opportunity to test the app during two laboratory alcohol drinking sessions and outside the lab in which you can use this technology in actual drinking situations. Your participation can last approximately 2 months.

b) What is involved with your participation, and what are the procedures to be followed in the research?

Your participation will first include an initial screening appointment to establish your eligibility status. If eligible, you may be invited to participate in 1) an individual alcohol drinking session 2) a group alcohol drinking session; 3) use of smartphone technology on your own in actual drinking situations for four weeks; 4) a follow-up appointment; and 5) a 6 & 12 month web-based follow up survey.

Some participants may be invited to complete only the field use period portion of the study. These participants will either be asked to use the app on their own in actual drinking situations for four weeks or will be prompted to complete multiple assessments on their phone each day for 10 days.

c) What are the likely risks or discomforts to you?

Some potential risks for you include breach of confidentiality; health risks from drinking alcohol; and maybe uncomfortableness in answering some questions.

d) What are the likely benefits to you or to others from the research?

This study may not have a direct benefit to you. Going forward, use of this smartphone application may help you to moderate your drinking. Others could possibly benefit from the information you provide us regarding the smartphone application and its effect on reducing alcohol drinking and related consequences.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

No clinical care is provided. Your participation is for research purposes only and is not to treat or diagnose any disease. Should you choose not to take part in this study, we can give you information about programs (research and internet) that can help you reduce drinking if you are interested.

A description of this research study 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.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

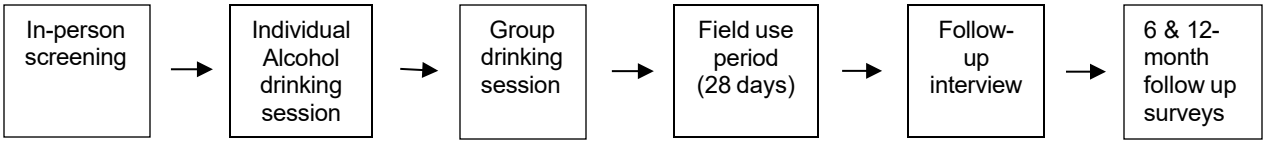
6. What will be done as part of your normal clinical care (even if you did not participate in this Research Study)?

"Normal Clinical Care" means procedures that would normally be conducted as part of the treatment for patients with a particular problem. No clinical care is provided, and this is not a treatment study. Should you choose not to participate in this study there will be no penalty or loss of benefits you are otherwise entitled to (such as your health care outside the study, the payment for your health care, and your health care benefits). All of your participation is for research purposes only, and not to treat or diagnose any disease. If you are currently interested in changing your drinking behavior, we will provide you with treatment referrals and you will not be eligible to participate in this study.

7. What will be done only because you are in this Research Study?

Description of Procedures

There are 6 possible phases to this study: 1) screening; 2) the individual alcohol drinking session; 3) the group alcohol drinking session 4) use of smartphone technology on your own in actual drinking situations for 4 weeks; 5) follow-up appointment at the end of the 4-week period; and 6) 6 & 12-month follow up survey.



Some participants may be invited to complete only the field use period portion of the study. Participants will either be asked to use the app on their own in actual drinking situations for four weeks or will be prompted to complete multiple assessments on their phone each day for 10 days.

Screening Phase:

The in-person screening appointment will take about 1-2 hours. If you are asked to complete only the 4 week field test portion, parts of the screening can be done remotely by phone, or password-protected UF Zoom meeting. In this appointment, we will interview you about your drinking habits, cigarette use, mood, patterns of decision-making, menstrual cycle if female, medical and mental health histories, and you will complete a computer reaction time task. To be eligible for the study, you will need to complete the task at around an average level compared to other participants. On your own time after the appointment, you will also be asked to complete a web

questionnaire that covers topics including demographics; drinking history; types of effects of alcohol use you have experienced in the past, recently and currently from drinking and the types of affects you expect from drinking (for instance, feeling more social, stumbling or slurring speech when drinking); possible difficulties in limiting alcohol use; reasons for drinking; negative consequences of alcohol use; depression and anxiety; possible family history of alcohol use; steps you may take to moderate your alcohol use and avoid negative consequences; and perceived risks and benefits of engaging in certain sexual behaviors.

You will be asked to provide breath samples for analysis with the use of a hand-held breathalyzer and to provide a urine sample for drug testing and pregnancy testing, if female. We will also take readings of your vital signs (blood pressure and pulse) and get your weight and height.

The alcohol drinking that is part of this study may not be safe for those who are also using cocaine, opiates, phencyclidine, amphetamines, methamphetamine, barbiturates, methadone or benzodiazepines. For this reason, if your urine drug test indicates use of one of these drugs, you will not be able to participate in the study. It is important that participants begin the alcohol drinking sessions with no alcohol in their system. A positive breath alcohol test at the in-person screening appointment raises concerns that an individual may not be able to present for the session without alcohol in their system. If you arrive with a breath alcohol reading between 0.01-0.02%, you may be able to remain at our research office until your breath alcohol level declines to 0.00% and then continue with the appointment or reschedule the appointment one time. However, if you arrive at an appointment with a positive breath alcohol reading a second time, you will not be able to continue participation in the study. We will not be able to provide any compensation for any appointment that ends with dismissal due to a positive urine drug test or positive breath alcohol reading. It is also not safe for women who are pregnant, nursing, or who may become pregnant to take part in the alcohol drinking part of this study. Therefore, women who are pregnant, nursing or sexually active without use of birth control will not be able to participate in the study.

Those recruited remotely will not be asked to complete a pregnancy test or a urine drug test. You will receive $30 for completing the remote recruitment session.

After you complete the in-person screening appointment, you will receive $10 if the appointment takes an hour or less and $30 otherwise. If you are eligible for the study, you will first be scheduled for an individual drinking session and then a group drinking session with 1-2 other participants on a day that is convenient for you.

Individual alcohol drinking session

At the designated appointment time, you will arrive at the research facility where the session will take place. Once you arrive, you will be asked to take a breath test with a breathalyzer. If your breath alcohol level is positive, you will not be able to take part in the study that day. Next, you will undergo a urine drug test, and women will receive a urine pregnancy test. Following the urine test, we will then measure your vital signs. We will update information regarding medical and mental health histories

and menstrual cycle for females. After, you will be given a small snack and a glass of water. Next, we will go over instructions for the session with you and ask you to agree to neither drive nor operate other heavy machinery for the rest of the night after you leave the research facility. You will then be asked to complete an online questionnaire that contains questions about your drinking behaviors. After completing this questionnaire, study staff will collect your phone and you will be given a study smartphone that has your randomly assigned form of mobile technology. Before the alcohol drinking part of the session, you may be asked to wear a BACTrack Skyn alcohol wristband monitor, which looks like a fitness tracker or wristwatch and can detect alcohol as it evaporates through the skin.

After completing this first portion of the session, we will begin the alcohol drinking part of the session. The amount of alcohol you are asked to drink is designed to lead to a breath alcohol concentration of 0.06%, based on your birth sex (male or female) age, height and weight. However, because people process alcohol differently, it is possible you may or may not reach that exact level. You will be able to watch the bartender pour each drink for you. You will have 10 minutes to consume each beverage. We ask that you space each of the three drinks out over the 10-minute period and to consume each beverage at your own pace. The alcohol-drinking period will last for 30 minutes. During this time, the only alcoholic drinks you will be allowed to have will be three vodka drinks provided to you by the study. After the completion of all three drinks, you will be asked to drink a small glass of water and then give another breath alcohol reading. After a 15-minute waiting period, you will use your randomly assigned smartphone application and receive personalized feedback on your performance.

After the completion of the alcohol drinking and app use, you will be required to remain in the research facility for at least two hours until your breath alcohol has dropped to the safe level of 0.02% or lower. During this time, you may partake in activities such as watching television or playing games. We will take back the study cell phone from you and return your own cell phone. When your breath alcohol reaches a safe level, you will be provided transportation directly home by the study. If you live within a 0.5 miles of the research facility, we may walk you home. This transportation can only be taken directly home. For your safety, it will not be possible for you to drive yourself home or for you to have a friend or family member pick you up. Payment for the session will be $10 per hour.

Table. 1 Summary of procedures for the individual drinking session	
Time	**Procedures**
+0	Arrival. Breath alcohol (BrAC) reading, urine testing, snack, US-THRIVE, app assignment, app information, & instructions, use app.
+60	Alcohol dosing period: dose targeting BAC=.06, divided into three parts, 10 minutes to drink each part of dose
+90	15 minute absorption period, participant drinks small glass of water to rinse alcohol from mouth
+105	BrAC, use app, self-report of perceived impairment & other measures, then BrAC
+135	BrAC, use app, self-report of perceived impairments & other measures.
+165	BrAC. Dismissal once BrAC ≤ .02%

Group Alcohol drinking session:

The alcohol drinking session is summarized in Table 2 below. At approximately 4:00 pm, you will arrive at the simulated laboratory where the session will take place. Once you arrive at the simulated laboratory you will be asked to take a breath test with a breathalyzer. If your breath alcohol level is positive, you will not be able to take part in the study that day. Next, you will undergo a urine drug test. Women will additionally receive a urine pregnancy test. Following the urine test, we will measure your vital signs. We will update information regarding medical and mental health histories and menstrual cycle if female. After, you will be provided a small snack and a glass of water. Next, we will go over instructions for the session with you and ask you to agree to neither drive nor operate other heavy machinery for the rest of the night after you leave the simulated lab. Study staff will then collect your phone and you will be given a study smartphone that has your randomly assigned form of mobile technology. You may be asked to wear a BACTrack Skyn alcohol wristband monitor, which looks like a fitness tracker or wristwatch and can detect alcohol as it evaporates through the skin. If your schedule does not allow attendance at 4pm, we can schedule this appointment either earlier on the day of the session or (if this is the only possible way to schedule it) the day before. If we hold the appointment on the day before, your urine test will still be on the day of the session. Compensation will be $20 for this preliminary appointment.

At 5:00pm, you will be provided your first of three alcoholic beverages. The amount of alcohol you are asked to drink is designed to lead to a breath alcohol concentration of 0.06%, based on your birth sex (male or female) age, height and weight. However, because people process alcohol differently, it is possible you may or may not reach that exact level. You will be able to watch the bartender pour each drink for you. You will have 10 minutes to consume each beverage. We ask that you space each of the three drinks out over the 10-minute period and to consume each beverage at your own pace. The alcohol drinking period will last for 30 minutes. During this time, the only alcoholic drinks you will be allowed to have will be three vodka drinks provided to you by the study.

Table 2. Summary of procedures for the group drinking session	
Time	**Procedures**
3pm	(approximate time) You will be brought to the simulated lab for the session
4pm	You will provide a breath alcohol reading, urine sample for analysis of illicit drugs and pregnancy, if female. Vital signs will be measured. We will go over instructions for the session with you. Review how to use a computer-based app.
5pm	Alcohol drinking period begins. You will have 30 minutes to consume 3 alcoholic beverages. You will then use the smartphone application and receive personalized feedback. Following the application use, there will be another alcohol drinking period lasting 1 hour.
7:15	Alcohol drinking period ends. You will receive a small glass of water to rinse alcohol from mouth followed by a short break. You will use the smartphone application again and receive personalized feedback.
8pm	Food, your phone returned and staff extracts data from the study phone.
10pm	You will complete questionnaires about the smartphone application you used. You will then learn about the four-week field use period.
11pm	The earliest time you can be brought home by the study. Once your BrAC ≤.02%, you will be sent home via study-provided transportation
[1] All times are approximate	

At 5:30pm, the first alcohol drinking period will end. You will be asked to drink a small glass of water and then give another breath alcohol reading. After a 15-minute waiting period, you will use your randomly assigned smartphone application and receive personalized feedback on your performance.

At 6:15pm, you will have another chance to drink alcohol, if you choose to do so. During this time, the only alcoholic drinks you will be allowed to have will be vodka drinks provided to you by the study. You may order as many drinks as you would like, but for safety reasons, we will be keeping track of your eBAC during the session using a chart that will be made especially for you. This chart provides an eBAC for each beverage someone consumes in a given period of time based on weight and sex. If your eBAC goes over the highest level allowed in the study, you will not be able to order any more vodka drinks until your eBAC drops below this level.

Your access to alcohol will end at 7:15pm. You will be asked to drink a small glass of water and then give another breath alcohol reading. After a 30-minute waiting period, you will use your randomly assigned smartphone application and receive personalized feedback on your performance. After these study tasks, you will be required to wait in the research office until at least 11:00pm and your breath alcohol drops to the safe level of 0.02% or lower. During this time, you may take part in activities like watching television and playing games. You will not be permitted to complete work during the session (either academic or for your job). You may also continue to order non-alcohol drinks, which the study will provide. You will also be

given food at no cost to you. We will take back the study cell phone from you and return your own cell phone.

Beginning at 11:00pm, when your breath alcohol reaches a safe level, you will be provided transportation directly home by the study. If you live within 0.5 miles of the research facility, we may walk you home. This transportation can only be taken directly home. For your safety, it will not be possible for you to drive yourself home or for you to have a friend or family member pick you up.

Payment for the session will be $10 per hour for a total of $60, plus an additional $20 for adhering to all rules in place for the session.

Four-week field use period:

You will be asked to use the smartphone application used in the study on your own for a four-week period. You will be asked to attend a baseline appointment when study staff will show you how to download and use the app to gather baseline data. You will then be pinged either later that day or the following morning to use the app again. Compensation for this appointment will be $10. Following your baseline appointment, you will attend an orientation appointment. Compensation for this appointment will be $10. Each morning during the four-week period, the app will ask you a short series of questions about your drinking the night before. For two of the four weeks, the app will also prompt you to play the same cognitive game you played when you use the app during the alcohol drinking session. The app will then give you feedback about your performance on the game. We ask that you grant the application permission to send you notifications so that study staff can set up the app so that it prompts you to use it three times on days/night, based on your typical drinking patterns. When you use the app, each time, it will ask you a brief set of questions about your drinking and related questions (for instance, about how impaired you feel at the time and about how much you want and would like more alcohol). Compensation will be $5 per day for answering the morning questions on the app plus a bonus of $5 for completing these questions 7 out of 7 days in a week, for a total of up to $40 per week. You will also be compensated $10 per week for using the app at least once per week during an alcohol drinking situation during the two weeks when you have full access to the app for a total of up to $20. Total possible compensation for the 4-week field use period is $200.

While we prefer that you use the app on your own phone, we understand that some people may not own a smartphone or may not want to use their own phone for this purpose. Therefore, you will be able to use a study smartphone instead of your own phone for this purpose with the following two conditions: 1) If the study smartphone is damaged or lost during the time when you are using it, we will deduct $50 from your payment for participating in the study. 2) You must use the study smartphone only during times when you are drinking and not for personal use outside of that. To participate in the study, you must either agree to use your own smartphone during the 4-week period or agree to use a study smartphone with these conditions. You do not have to decide now whether or not you want to use your own phone. If you are eligible for the study and take part in it, we will ask for your final decision on the day of the alcohol drinking session. Data collected by the app will not be visible after it is

submitted so minimal information about you will be visible in the app if your phone is stolen, lost, “hacked” or in some other way made visible to another person. Even though task performance and questionnaire responses are no longer visible after submission, we suggest that all participants password protect their phone, and change the auto lock to 1 minute so that the application cannot be accidently accessed by anyone other than you. At the session, should you choose to use a study smartphone during the four-week field use period, we will ask you to sign a statement that you understand and agree to abide by these two conditions. You will be given the study app to use on your phone and you will be allowed to keep it after the study ends. If you are participating remotely, you must use your own smartphone to participate and it must be an iPhone.

Statement regarding phone use: I understand that to take part in this study I must agree to either use my own smartphone during the 4-week field use period after the alcohol drinking session and allow study staff to take my alcohol drinking and study-related mobile technology use data from my phone or use a study-provided smartphone with these two conditions: 1) If the study smartphone is lost or broken while I am using it, $50 will be deducted from my participant payment. 2) I will only use the study smartphone during times when I am drinking alcohol and not for personal use at other times (for example, at work, for talking/texting between classes). By initialing, I indicate that I am willing to follow these conditions: _____

Field Testing with Multiple Daily Assessments:

You will be prompted 5 times a day for 10 days to complete brief assessments on your phone. On days that you drink you may complete up to 7 assessments. You will be prompted in the morning to complete a daily questionnaire via the app that will capture your drinking in the past 24 hours. You will then be prompted twice daily to complete assessments and the cognitive task using the app on your phone. On days that you usually drink you will complete two more surveys that will be sent to you by the study staff. You will receive a reminder by text between an hour and two hours before your normal drinking time asking you to complete a brief drinking questionnaire. This questionnaire will be sent by text message and should be filled out at the end of each of your first three drinks .This survey will ask about what the you are drinking, the time it took you to have your drink, how you are feeling at time, the situation in which you are drinking, and your location (i.e. at home, bar, restaurant, friend’s house, etc.) At the end of the night, about an hour to two hours before your typical bedtime, you will receive another notification to complete an end of the night survey. This survey will ask about your total number of alcoholic drinks for that day/night, what time you finished drinking, how you are feeling, how impaired you think you are, and about ability to limit your alcohol use. You can receive up to $130 if you complete ≥ 80% of the possible questionnaires. You will receive a prorated portion of the $130 if you complete less than 80%. For instance, 50% completion would earn $65.

Follow-up appointment:

After the four weeks of field use, you will attend an appointment at the research office, which should last about an hour and a half. You will be compensated $30 for

this appointment. We will review with you what went on during the study and get your feedback about your experiences as a participant. Staff will take data on your alcohol drinking and use of the mobile technology we are testing in the study during the four-week field use period from your smartphone or the study smartphone. You will be able to watch study staff as they do this. After the data are removed from the phone, the data will be deleted from the smartphone. We will make arrangements for you to receive whatever payment you are owed.

Six- & 12-month follow ups: Six and twelve-months after completion of the group drinking session, you will be contacted by electronic mail, text, and/or phone and will be asked to complete a survey made up of questions similar to those you answered previously in the study. The survey will be completed through the secure website. Payment for completion of each survey will be $25.

Participant Obligations

Participation in other studies:

While you are actively taking part in this study, please do not sign up for any other studies without first letting us know and telling us about the details of this other study. Some studies conflict with one another as to what they ask participants to do. For that reason, it may not be possible for you to do this study and another study at the same time. In that case, it will be up to you to decide which study you would like to take part in first.

Honesty and arrival at all sessions:

We rely on participants to give us honest and accurate information on all study interviews on and on all questionnaires, so please answer all of these as completely and honestly as possible. While it is normal for life circumstances to make it challenging to keep scheduled appointments, please try to arrive as scheduled for all study appointments or to let us know by email or phone if you will not be able to attend or if you will be late.

Drug/alcohol use and safety:

Please avoid using illegal drugs while taking part in this study and please follow our request not to drink alcohol on the day of the session. After the end of the alcohol drinking period in the session, we will ask that you stay at the research facility until your breath alcohol reaches 0.02% or lower. You will then be brought directly home by a professional transportation service or an automobile owned by the University of Florida, driven by study personnel.

If you decide to leave the research facility before your breath alcohol level drops to 0.02% or lower, we will still give you the same transportation to your home. Should you decide to stop participating, you would be provided all money that you have earned up to that point on a prorated basis.

Our requests that you remain at the research facility until your breath alcohol level declines to 0.02% are to protect your safety, so we ask that you please abide by these rules.

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in question 3 of this form.

8. What identifiable health information will be collected about you and how will it be used?

The Research Team will collect get information that identifies you and your personal health information. This may include information that might directly identify you, including your name, date of birth, telephone number, postal address, email address and social security number. These materials that may personally identify you will be stored in a locked cabinet separate from study data. A list that includes both study identification numbers and participants' names will be stored in another, separate locked cabinet. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. If, based on information you provide during the in-person screening appointment, you are considered ineligible to participate further, we will retain your study-related data for the duration of the study. All information you provide us will be kept in locked filing cabinets in the Yon Hall North research facility and your protected health information will be kept in separate locked filing cabinets.

Specifically, the following information may be collected, used, and shared with others:

- Research study records
- Records about phone calls, email and text message communication made as part of this research
- Records about your study visits
- Results of urine drug screens and pregnancy tests (though the test devices themselves will be destroyed)
- Responses regarding your health provided on questionnaires and in interviews
- Information regarding the use of illegal drugs
- Data about use of technology that measures blood alcohol concentration

This information will be stored in locked filing cabinets or on computer servers with secure passwords or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the

limited data set are required in order to protect your identity and confidentiality and privacy.

The Research Team and the University of Florida Institutional Review Board (IRB), may collect your health information as part of this study.

The Research Team listed in question 3 above will use or share your health information as described below to carry out this research study.

9. With whom will this health information be shared?

This health information may be shared with:

- the study sponsor (listed in Question 4 of this form);
- United States governmental agencies which are responsible for overseeing research, such as the Department of Health and Human Services, and the Office of Human Research Protections;
- Government agencies which are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.
- The IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law.

10. How long will you be in this Research Study?

You participation will last approximately 2 months. This includes the screening process.

This Authorization to use and share your health information expires at the end of the study, unless you revoke it (take it back) sooner.

11. How many people are expected to take part in this Research Study?

A total of 208 participants sign a consent form and enroll in this study with 109 participants expected to be eligible and begin the study. Of these, 99 participants are expected to complete the lab drinking session and 4-week period afterward.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

12. What are the possible discomforts and risks from taking part in this Research Study?

Breach of confidentiality:

Our study will collect data on alcohol and substance use and other sensitive health behaviors. Breach of confidentiality could occur in our process of communicating with you, loss of research data, and transfer of data. Precautions are taken to ensure that all research materials are not accessible to anyone other than the study investigators. Whenever possible, research participants will be referred to by study-assigned ID numbers rather than by their name or other personal information. Accordingly, results of interviews and questionnaires, breath alcohol concentration, and urine drug/pregnancy screening are recorded by staff members on paper forms using study IDs only.

Some private identifiable information about individuals will be collected to enroll and contact participants. This information will be collected primarily via paper forms, which will be stored in locked filing cabinets at the research facility and only be accessible by study staff and other authorized individuals (e.g., members of the University of Florida Institutional Review Board). This includes a master list connecting participant study identification numbers to participant names.

Research data will be entered and stored on a secure server at the University of Florida, with no identifying information. All study data will be linked using study ID. No data in the research data base will have participant's PHI. No results will be published in a personally identifiable manner. Data from the app will be stored on Amazon's AWS database with no personal identifiers other than your randomly assigned study ID number. Amazon's AWS is approved as secure by University of Florida Information Technology and Amazon AWS currently has a Business Associate Agreement with the University of Florida. Study staff will download data off the Amazon site regularly. The downloaded data will be stored on a secure server and secure computers.

If you decide to take part in this research study, you will be required to give us information about your substance use behavior. A Certificate of Confidentiality (CoC) has been issued by the National Institutes of Health (NIH) for this research study. CoCs are issued by the NIH to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative or other proceeding, whether at the state, federal or local level. CoCs are granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability or reputation. The protection offered by the CoC does not stop us from voluntarily reporting information about suspected or known sexual, physical, or other abuse of a child or older person, or a subject's 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. The CoC also will not cover any information transmitted to the makers of the smartphone apps used in this study, however the makers of the apps do not receive information that could identify you as an individual. Once your data are downloaded off the smartphone, onto our study computer, the data are then covered by the CoC. Again, data will be deleted off the smartphone after downloading is complete.

Even when a CoC is in place, you and your family members must still continue to actively protect your own privacy. If you voluntarily give your written consent to anyone or share/discuss with anyone information about your participation in the research, then we may not use the CoC to withhold this information.

Alcohol consumption:

Several medical conditions could be made worse by drinking alcohol in large amounts over a relatively short period of time (for example, liver disease, cardiac problems, pancreatitis, diabetes, neurological problems, and gastrointestinal disorders). If you have any of these medical problems you should not take part in this study. Alcohol may also cause nausea in high doses; however, nausea is not expected at the doses in this study. Although it is unlikely that you will experience difficulty with motor coordination from drinking alcohol in this study, we will monitor you closely during the alcohol drinking session to avoid possible accidents such as falls. For your safety, we will require that you remain in the simulated laboratory where the alcohol drinking session takes place until your breath alcohol reaches the safe level of 0.02% or lower. Alcohol is a reinforcing agent (for instance, people often report good feelings while drinking alcohol), which may cause changes in behavior including repetitive or excessive alcohol drinking. We do not endorse drinking alcohol in the amounts used in this research study.

Questionnaires and interviews:

The questionnaires and interviews you will complete for this study include topics like mood, mental health, drug and alcohol use and the alcohol use history of members of your family. While these questions are not usually considered invasive, some questions require personal information. If you endorse current thoughts about suicide or inflicting harm upon yourself, we will notify study physician Dr. Cook and/or call 911. You are free to refuse to answer any question, although this may affect your eligibility for the study, should you refuse to answer questions that are part of the screening process.

Smartphone and smartphone app use:

Use of smartphones and an app is an important part of this study. Use of this technology carries with it a small degree of risk. Smartphone apps typically obtain minimal information from users (for instance, their general geographic location), however they do not obtain protected health information (for instance, the user's phone number). If you lose either your own smartphone or a study smartphone during the 4-week field use period in this study, there is a degree of risk because someone who finds the phone may be able to use information on the phone in a way that is damaging to you. However, this risk should be no greater than the risk you typically

have in using your own cellphone. If you use a study smartphone rather than your own phone during the 4-week field use period, you take on responsibility for the phone If the phone is lost or damaged during your time in the study, you may have a portion of your payment deducted to make up for replacement costs of these items. At the follow-up appointment after the 4-week field use period, we will remove data on your alcohol drinking and use of the mobile technology we are studying from your own smartphone or the study smartphone, depending on which you used during this period. Study staff will remove the data while you are there so you can rest assured that your privacy will be maintained. All text messages and phone records will be deleted from the study smartphones and from the backups in the phone "cloud" at the end of each person's time in the study.

Urine samples and pregnancy:

Urine sampling and testing for use of cocaine, opiates, phencyclidine, amphetamines, methamphetamine, barbiturates, benzodiazepines and methadone and urine pregnancy screening for females are non-invasive and should not add any risk. Urine samples will not be kept by the study after testing. Alcohol use is harmful to an unborn child. For this reason, pregnant women will be excluded from this study.

BACTrack Skyn:

The wrist biosensor is a noninvasive device shaped like a fitness tracker with a sensor for alcohol. Wearing it adds no risk other than that associated with similar devices, for example, wearing the device too tightly. The device is adjustable for different wrist sizes, and you will not be required to wear the wrist sensor if you do not want to. The data will be stored in the monitor without information that might identify you. The data will then be downloaded to secure UF drives after each lab session. Data from these devices and related information such as how much alcohol you report drinking and demographic information (e.g., your gender) may be combined with data from another study using these devices that study Co-Investigator Dr. Leeman collaborates on (IRB201801188). Dr. Wang, who is a collaborator on this study, directs study # 201801188. Besides Dr. Wang, no researchers working on study # 201801188 will see any information about you that identifies you personally.

Other participants and privacy:

You will complete the alcohol drinking session with other participants, which adds a potential privacy risk. We will avoid scheduling people who may know each other for the same alcohol drinking sessions. For instance, we will avoid scheduling people who live near each other. It is still a possibility though that you could end up in a session with someone who you know. You and all others in the study will be asked not to disclose the identities of others who complete the study along with them and not to disclose their behaviors during the sessions (for instance, how much alcohol they consume). Study staff will not give out any personal information about you. Please be careful not to disclose any personal information that you would like to remain private to any bar staff. Study staff typically refer to people in the study by their first name only during drinking sessions. However, we would be happy to refer to you by another name if you prefer not to disclose your real name to others in the study.

This Research Study may also include risks that are unknown at this time.

Please note, participating in more than one research study or project may further increase the risks to you. If you are already enrolled in a research study, please inform one of the Research Team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

During the study, the Research Team will notify you of new information that may become available and might affect your decision to remain in the study.

The University of Florida is required by law to protect your health information. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by University policy. However, there is a slight risk that information about you could be released inappropriately or accidentally. Depending on the type of information, a release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the Research Team members listed in question 3 in this form.

13a. What are the potential benefits to you for taking part in this Research Study?

There are no direct benefits to you as a participant. However, it is possible that you could benefit from awareness of problematic drinking behaviors in which you may be engaging and from the use of the experimental app.

13b. How could others possibly benefit from this Research Study?

Should you choose to participate, others could possibly benefit from the information you provide us regarding the use and feedback of the smartphone application.

13c. How could the Research Team members benefit from this Research Study?

In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in question 3 of this form may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals. There are no other conflicts of interest.

13d. Will you be allowed to see the research information collected about you for this Research Study?

You may not be allowed to see the research information collected about you for this Research Study, including the research information in your medical record, until after the study is completed. When this Research Study is over, you will be allowed to see any research information collected and placed in your medical record.

14. What other choices do you have if you do not want to be in this study?

Should you choose not to take part in this study, we can give you information about programs (research and internet) that can help you reduce drinking if you are interested.

You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

15a. Can you withdraw from this study?

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in question 3 of this form to let them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in question #3.

15b. Can the Principal Investigator withdraw you from this Research Study?

You may be withdrawn from this Research Study without your consent for the following reasons:

- Adverse reactions to alcohol use in the course of the study
- Any medical conditions that make alcohol use especially unsafe for you that come to light after you begin the study.
- Not being entirely truthful with the information you provide to us
- Not arriving for appointments for the study as scheduled
- Other instances of not following study procedures

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

16. If you choose to take part in this Research Study, will it cost you anything?

No. There will be no extra cost to you for participating in this Research Study.

17. Will you be paid for taking part in this Research Study?

Compensation is up to $450. Should you end your participation at any point before the end of the study, you will be compensated on a prorated basis for all parts you have completed up to that point. Payment can be broken down as follows: $30 for the in-person screening appointment; $20 for the pre-session appointment that happens wither earlier in the day or just before the actual alcohol drinking session; $10 per hour for the individual and group alcohol drinking sessions for a total of $100 plus another $20 for adhering to the rules of the session; up to $200 for the four-week field use period; and $30 for the follow-up appointment; and $25 for each completed follow up survey.

Because some participants will be paid more than $75 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. Payments to nonresident aliens, must be processed through the University of Florida payroll and Tax Services Department.

Accounts Payable department and the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: http://privacy.ufl.edu/SSNPrivacy.html.

Your payment for participation in this research study is handled through the University of Florida's Human Subject Payment (HSP) Program. Your information, which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (HSP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

We will provide you with an informational form called the Prepaid Card Facts document. If you have any problems regarding your payment call the HSP Office (352) 392-9057.

18. What if you are injured while in this Research Study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or

psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact one of the Research Team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this Research Study.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this Research Study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing Date