UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. 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.

If you want to talk with someone independent of the research team for questions, concerns, or complaints about the research; questions about your rights; to obtain information; or to offer input, you can also contact the Florida Department of Health (DoH) Institutional Review Board. You can contact the FL DoH IRB at: 850-245-4585.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

Advancing New Computer-based Health Outreach Regarding Sexual behavior (ANCHORS) Study: Usability Study

3. Who do you call if you have questions about this research study?

Principal Investigator: Robert F. Leeman, Ph.D., FLG Room 14, 352-294-1808

Co-Investigators: JeeWon Cheong, Ph.D., FLG Room 19, (352) 294-1811; Robert Cook, M.D., M.P.H., CTRB Room 4232, (352) 273-5869; Jalie Tucker, Ph.D., M.P.H., FLG Room 5C, (352) 294-1812
Study Coordinators: Benjamin Berey & Tessa Frohe, Yon Hall North, Room 016, 352-294-1026

4. Who is paying for this research study?

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

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 this research, how long will you be involved?

The purpose of this study is to get participants' input about a mobile survey with personalized information that we are developing to help young adult men to reduce their alcohol use; improve their sexual health behaviors and prevent HIV infection. This is a separate web survey from the prior ones you completed for this study. You have been invited to take part because you are between the ages of 18-30, drink alcohol regularly, met all criteria to be included in the study, and completed the first part of the study (an initial survey followed by a 30-minute survey on the web). Your participation will last just over 1 month.

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

Participation will include completion of the web-based survey with personalized information regarding alcohol, other substance use and sexual health behaviors; daily assessment using a telephone-based system; and providing your opinions on the mobile survey with personalized information including how we can improve it for future studies.

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

Completion of web- and telephone-based surveys brings with them a confidentiality risk but we take steps to decrease those risks. Your responses to the web and phone-based assessments will be protected through our use of a secure system for administering these assessments and encrypted transmission of data.

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

This study may not have a direct benefit to you. It is possible that you could benefit from personalized information about your alcohol use and sexual activity, and others could benefit from your feedback and suggestions regarding the web- and telephone-based surveys

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

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 your alcohol intake or change your sexual behavior if you are interested.

This consent form gives you detailed information about the study so you know enough about its risks and benefits to make an informed decision about whether or not you would like to participate. This discussion will include all aspects of this research: its purpose, procedures that will be performed, risks and possible benefits. After we discuss this information, you will be asked if you wish to participate. If so, you will be asked to sign this form.

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)?

In this study, you will be asked to complete a web-based, mobile survey followed by daily, brief telephone based assessments. Your responses to these questions on the web and by phone will allow us to provide you personalized information on your alcohol use and sexual behavior. We will then ask you to give us your opinions about the survey and information along with suggestions for improvement. This is not a clinical study and therefore participation in this study will not have an impact upon your normal clinical care.

7. What will be done only because you are in this research study?

Overview: You study participation can be broken down into the following **3**steps.

1) Completion of the web-based survey with personalized information regarding alcohol, other substance use and sexual health behaviors. During this same appointment, we will show you how to access the telephone-based daily assessment system.
2) Daily assessment using a telephone-based system. Each daily assessment will take about 5 minutes to complete. We will ask you to complete these daily assessments for 30 days. Each week, you will receive personalized information about your alcohol use and sexual behavior based on your responses to the telephone based system.
3) After the 30-day assessment period, you will be asked to return to the research office to complete a survey similar to the first appointment and to give your opinions on the mobile survey with personalized information including how we can improve it for future studies.

The types of questions you will be asked and procedures you will be engaged in during the study are as follows:

Alcohol questions: In addition to demographic questions, height and weight, the first part of the survey includes questions on past-month drinking and patterns of alcohol use. You will then receive personalized feedback on your risk level, an estimated blood alcohol concentration from your highest recent drinking day in the past month, a comparison between your alcohol use and alcohol use by peers of a similar age as you as well as estimated money spent on alcohol. There will also be tips, facts, and support available when taking this survey.

Questions on sexual behavior: You will also answer questions about your sexual activity in general along with substance use on days when you have engaged in sexual activity. Afterwards, you will be presented with feedback that compares your responses to results from peers of similar age.

Daily telephone-based assessment questions: You will be asked to provide a phone number where we can reach you. This number will be entered into an automated phone system created for this study. The system will call you each day up to 3 times to prompt you to complete your daily assessment. You can also call the system back yourself if you miss one or both of these prompts. If you miss a day, you will have the option to call a separate phone number and leave your daily responses on a voicemail.

Each day as part of this assessment, you will be asked questions about the day before including whether you drank alcohol or used other substances; whether you engaged in sexual activity with a regular or other sexual partner; whether protection was used and whether the activity was with a member of the same or opposite sex. You will also be asked about whether you used alcohol or other substances before this sexual activity. One of the ultimate goals of these surveys and personalized information is to increase participants' use of a particular type of medication. For this reason, you will also be asked a question about use of medication, however, this is not a medication study. So instead, you can reply as to whether or not you completed any health-related behavior that is important to you.

Based on these responses, each week you will be provided personalized information including your results compared to that of your peers. This personalized information will include number of drinks per week; days of protected/unprotected sex compared to normative data, number of days taking medication/completing other health activity; the instances you had protected/unprotected sex following alcohol drinking versus not; and medication taking/other health activity on drinking vs. non-drinking days. This feedback will be mailed to a postal address or posted to a secure, password-protected webpage (whichever you prefer). This assessment will require about 5 minutes per day.

Follow-up appointment: After the 30-day daily assessment period, you will attend an appointment at the research office, which should last about an hour. You will be asked to complete assessments similar to the first appointment. We will also ask for your input about the mobile survey and personalized information and to offer your suggestions for ways we can improve it.

Honesty and arrival at all sessions: We rely on participants to give us honest and accurate information so please answer all questions completely and honestly. 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.
If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

Participation in multiple studies: Participating in more than one research study or project at a time may not be possible. If you are already enrolled in another 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.

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. How long will you be in this research study?

Your participation will last just over 1 month.

9. How many people are expected to take part in this research study?

A total of 1366 individuals will be screened for this study. Ten participants are expected to complete this portion of the study.

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

10. What are the possible discomforts and risks from taking part in this research study?

Web- and telephone based assessments: Completion of web- and telephone-based surveys brings with them a confidentiality risk but we take steps to decrease those risks. The assessments include questions about sensitive issues, namely sexual behavior and alcohol and other substance use. Answering these questions or receiving personalized information about your behaviors may increase your concern or worry about these behaviors. Information about ways to change these behaviors will be provided should this be of interest. You are free to skip any question you would rather not answer. However, if you would rather not respond to any questions about these issues, it would be best for you to not participate in the study.

The daily assessment phone calls will be managed through a cloud-based telephone services provider called Twilio Inc. Twilio's systems will make the phone calls, read survey questions, and send the responses you make using your phone back to the REDCap system, which we are using to conduct the surveys for the study. In order for this to happen, your phone number would be entered into the Twillio system, along with your survey responses. Twilio does not keep a record of these details though. Twilio records a log of what numbers where called when, but REDCap reduces any risk from that by deleting the call log from the Twilio system moments after the survey is completed. Thus any confidentiality risk from your completion of these phone call assessments will be minimal.

Confidentiality: Your responses to the web and phone-based assessments will be protected through our use of a secure system for administering these assessments and encrypted transmission of data. You will be identified in the survey data only by your study ID number. A paper log will be maintained that includes study IDs, participants names and other contact information but this information will be stored in a locked cabinet in a locked room. In order to compensate you for the prior web-based survey you completed, we entered your name and other identifiable information into a secure, web-based research participant payment system maintained by the University of Florida. We will be using the same system to compensate you for your participation today. None of your responses made on the web- or phone-based assessments will be combined with the information entered into the participant compensation system.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another 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.

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

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 or listed in question 3 of this form.

11a. What are the potential benefits to you for taking part in this research study ?

While our goal is for the results of this study to benefit our knowledge of interventions, this study may not have a direct benefit to you. It is possible that you could benefit from personalized information about your alcohol use and sexual activity. You may also benefit from information about ways to change your behaviors should this be of interest to you.

11b. How could others possibly benefit from this study?

Should you choose to participate, others could possibly benefit from the survey responses you give and from the information you provide us regarding the usefulness of the web- and phone-based assessments and personalized information regarding alcohol use and sexual activity. Also suggestions you provide about the surveys and personalized information and how to tailor them specifically for young men could improve its quality and increase its usefulness to others.

11c. How could the researchers benefit from this study?

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

12. 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 your alcohol intake or change your sexual behavior if you are interested.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to ensure that the study is conducted the way it is supposed to be and/or for study oversight.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- Providing responses that compromise the integrity of the project
- Not arriving for appointments for the study as scheduled
- Other instances of not following study procedures

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

No. There will be no extra costs to you for participating in the Research Study.

15. Will you be paid for taking part in this study?

Compensation for the first appointment will be $30. At this appointment, you will complete the web-based survey with personalized information and be trained in how to use the phone based system. For each day that you complete a brief telephone-based assessment during the 30-day period, you will earn $1 that will be banked in an electronic account. There is also a chance to earn 10 bonus points worth $2 each for completing 7 of 7 days in a week. If you miss a day you lose bonus points for the week but can recover 7 lost points for weeks with missing data if you do not miss more than 2 consecutive days. The automated phone system will call you up to three times a day until it is successful at reaching you. If you do miss a day, you may call a separate number and leave your previous day's responses in a voicemail. You will receive daily payment for "makeup" calls but these are not figured into bonus eligibility. For the last appointment after the end of the 30-day phone-based assessment period, you will earn $35. Maximum compensation including all of these

payments is $175. 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.

Given that participants may receive 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. 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.

16. What if you are injured because of the 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 the Principal Investigator 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 study.

17. How will your privacy and the confidentiality of your research records be protected?

Information collected about you will be stored in locked filing cabinets or in computers with security passwords. Only certain people have the legal right to review these research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, the hospital or clinic (if any) involved in this research, and the Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). Otherwise your research records will not be released without your permission unless required by law or a court order. Phone numbers are only for the purpose of the system contacting participants on a daily basis to complete their assessment. Phone numbers will be deleted from Twilio's system logs after completion of each call. At the end of the study, the telephone numbers will be removed from the data. Because of that, participant phone numbers will not appear as part of any data set that will be analyzed by any study collaborator.

Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.

If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.

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 alternatives to being in the study; and how privacy will be protected:

Signature of Person Obtaining Consent | 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 privacy will be protected. 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 other questions at any time.

You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting | Date