Title: Optimizing a Digital AEP Risk Intervention with Native Women and Communities

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Electronic Informed Consent Agreement

Study Title: Optimizing a Digital AEP Risk Intervention with Native Women and Communities
Protocol #: SBS6760

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

Purpose of the research study: The purpose of the study is to determine the optimal combination of novel intervention strategies to include with CARRII, the first automated digital AEP (alcohol-exposed pregnancy) intervention, tailored for Native women and others who can become pregnant, that maximizes digital intervention efficacy at a feasible cost for Native communities.

- Alcohol exposed pregnancy (AEP) can result in Fetal Alcohol Spectrum Disorders (FASDs) that cause lifelong costly disabilities from brain, organ, tissue, and neurological damage.
- While over 3.3 million US women per month are at risk for AEP, risk for AEP among Native American women is higher, due to low contraception use and high binge drinking rates.
- AEP can be prevented by avoiding an unintended pregnancy or reducing alcohol intake by those who may become pregnant.
- Because rates of unintended pregnancy and binge drinking that create AEP risk are inequitable between Native women and the general population, CARRII must be tailored to and optimized for Native women and others who can become pregnant.

What you will do in the study: Participants will pilot test new candidate components tailored to Native women at risk of AEP.

- You will complete a **baseline interview** including a telephone-administered 90-day Timeline Follow-Back (TLFB) of alcohol use and contraception use to determine eligibility, and two short online surveys evaluating knowledge about AEP risk, intentions and self-efficacy to change, and readiness to change alcohol and/or contraception behaviors.
- You will complete the 4 parts (Cores) of the CARRII Native internet intervention over the 6-week period
- You will also be **randomized to receive one new component**, for the 6-week period.
- There will be one interim phone call with a study leader, after 3 weeks in the pilot trial.
- After 6 weeks, you will complete: a second interview that includes a 6-week Timeline Follow-Back (TLFB) of alcohol use and contraception use, two short online surveys evaluating knowledge about AEP risk, intentions and self-efficacy to change, and readiness to change alcohol and/or contraception behaviors, and two surveys to rate the component you experienced and system usability.
- You can skip any survey question and you can stop the interview/survey at any time.

The five new components that will be tested by yourself and other participants are:

1. Telephone-administered 30-day Timeline Follow-Back (TLFB) calendar of alcohol intake and contraception type by sexual encounter, at enrollment and monthly (2 weeks after enrollment);

2. Mailed pregnancy tests sent monthly;
3. Automated, personalized digital safer sex and drink counting/reduction skills training;
4. Fully automated text messaging, prompting usage of safer sex and drink reduction skills;
5. Access to an anonymous Community Message Board of Native women.

Time required: The study will require from six and a half (6.5) to ten and a half (10.5) hours of your time, based on the following:

The baseline phone call and questionnaires will require about one hour of your time.

The 4 parts (Cores) of the CARRII Native internet intervention will take up to four hours to complete.

Each component tested over the 6-week period will require a different amount of time, depending on which one you are randomized to:

- Timeline Follow-Back telephone call at 2 weeks: 30 minutes
- Mailed pregnancy tests: 10 minutes
- Automated digital skills training: 1-2 hours
- Automated text messages: 60 minutes
- Community Message Board: up to 4 hours, depending on individual level of participation in online discussions

The interim (mid-study) phone call will require about 10 minutes of your time.

The end-of-study interview and surveys will require about one hour of your time.

Risks: Risk of inadvertent disclosure of sexual or drinking behaviors is a small risk. Data will be captured electronically and de-identified and results linked to your study identifiers rather than name, to minimize risk of inadvertent disclosure.

Several relatively smaller risks can occur. There are no known risks of participation in the study other than those commonly experienced with mobile technologies and being involved in AEP (alcohol-exposed pregnancy) studies. As with other studies, embarrassment or discomfort with some questions can occur. You do not have to participate or may only answer the questions that you feel comfortable in answering, and the surveys are confidential. We have access to mental health provider and medical staff both on our team and in the communities where we will recruit participants, in the event that you experience any emotional or psychological discomfort.

Benefits: There are potential benefits, such as an increased understanding of the importance of reducing AEP risk, improving contraception habits, or reducing drinking, which could reduce morbidity and mortality. By participating, you may also receive additional educational information and information about support systems available in your local areas, and you may elect to reduce drinking or improve contraception use.

Confidentiality: The information that you give in the study will be handled confidentially. Your information will be assigned a code number. The list connecting your name to this code will be kept in a file on a secured server. When the study is completed and the data have been analyzed, this list will be destroyed. Your name will not be used in any report. If you are randomized to the Anonymized Community Message Board, you will use a study name instead of your real name, and we will ask you not to write anything in the Board that could identify you to the other participants.

Voluntary participation: Your participation in the study is completely voluntary.

Right to withdraw from the study: You have the right to withdraw from the study at any time without penalty.

How to withdraw from the study: If you want to withdraw from the study, notify the study team by email, phone call or text message. There is no penalty for withdrawing You will still receive payment for any part of the study you have completed.

Payment: You will receive financial compensation for participating. For completing the baseline survey, you will receive a $25 e-gift card. After 6 weeks of using the test component and completing the follow-up surveys, you will receive a $75 e-gift card.

Using data beyond this study: The data you provide in this study will be retained in a secure manner by the researcher for up to three years and then destroyed. The study researchers may use a software application or an Artificial Intelligence (AI) program, like Chat GPT, to analyze data for this study, including your data. The researcher will remove any directly identifying information (such as your name, contact information, etc.) connected to the information you provide. This AI program may store your data outside of UVA for future use.

Please contact the researchers on the study team listed below to:

- **Obtain more information or ask a question about the study.**
- **Report an illness, injury, or other problem.**
- **Leave the study before it is finished.**

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You may also report a concern about a study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

Tonya R. Moon, Ph.D.
Chair, Institutional Review Board for the Social and Behavioral Sciences
One Morton Dr Suite 400
University of Virginia, P.O. Box 800392
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UVA IRB-SBS # 6760

You may print a copy of this consent for your records.

Electronic Signature Agreement:
I agree to provide an electronic signature to document my consent.

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