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

ClinicalTrials.gov ID: NCT06324929

Document date: 12-05-2024

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.

You are being asked to participate in this study because you are aged 18-44, Native American, and can become pregnant.

What you will do in the study: This study involves answering questions in an online survey. After you agree to participate and sign this consent form, the study coordinator will email the Qualtrics online survey link to you. You may access the survey on your mobile device or computer. The survey questions will ask about you generally, and about your alcohol use, sexual choices, use of methods to prevent pregnancy, use of mobile phones, and interest in subsequent related studies. Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go on to the next question. However, we ask that you try to answer every question.

Time required: The study will require about 35 minutes of your time.

Risks: A risk of allowing us to collect information about you is a potential loss of privacy. If you access the survey and don't submit it, there is the chance someone could see it on your phone, including answers you completed but did not yet submit. The University of Virginia will do their best to protect your records so that facts about you and your health will be kept private. The chance that information identifying you will be given to someone else is very small. However, we cannot guarantee it will be safe.

Benefits: There are no direct benefits to you for participating in this research study. All information gained from this study will be used to help create an app that can help people avoid having a pregnancy affected by alcohol in the future.

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 locked file. 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.

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, you may stop answering the survey questions. There is no penalty for withdrawing. You will still receive full payment for the study. If you would like to withdraw after your materials have been submitted, please contact the study coordinator.

Payment: Compensation for survey completion is a $20 e-gift card.

Using data beyond this study: Results of data analyses may be published in medical journals and/or presented at conferences. Any presentations or publications will be displayed in a way that does not identify you.

The data you provide in this study will be retained in a secure manner by the researcher for 3 years and then destroyed.

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.**

Principal Investigator's Name: Karen Ingersoll, PhD, ABPP
Psychiatry and Neurobehavioral Sciences
Room 3147
560 Ray C. Hunt Drive
Charlottesville, VA 22908
Telephone: (434) 982-5960
Email: kes7a@uvahealth.org

Study Coordinator: Silvia Park, CCRC
Psychiatry and Neurobehavioral Sciences
560 Ray C. Hunt Drive

Charlottesville, VA 22908
Telephone: (434) 924-3991
Email: spp2d@uvahealth.org

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
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 # SBS6760

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.