# Title: CARRII Native Intervention Optimization Trial

NCT ID (not yet assigned):

Document date: 2026-04-06

# Electronic Informed Consent Agreement

Study Title: CARRII Native Intervention Optimization Trial
Protocol #: SBS7390

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

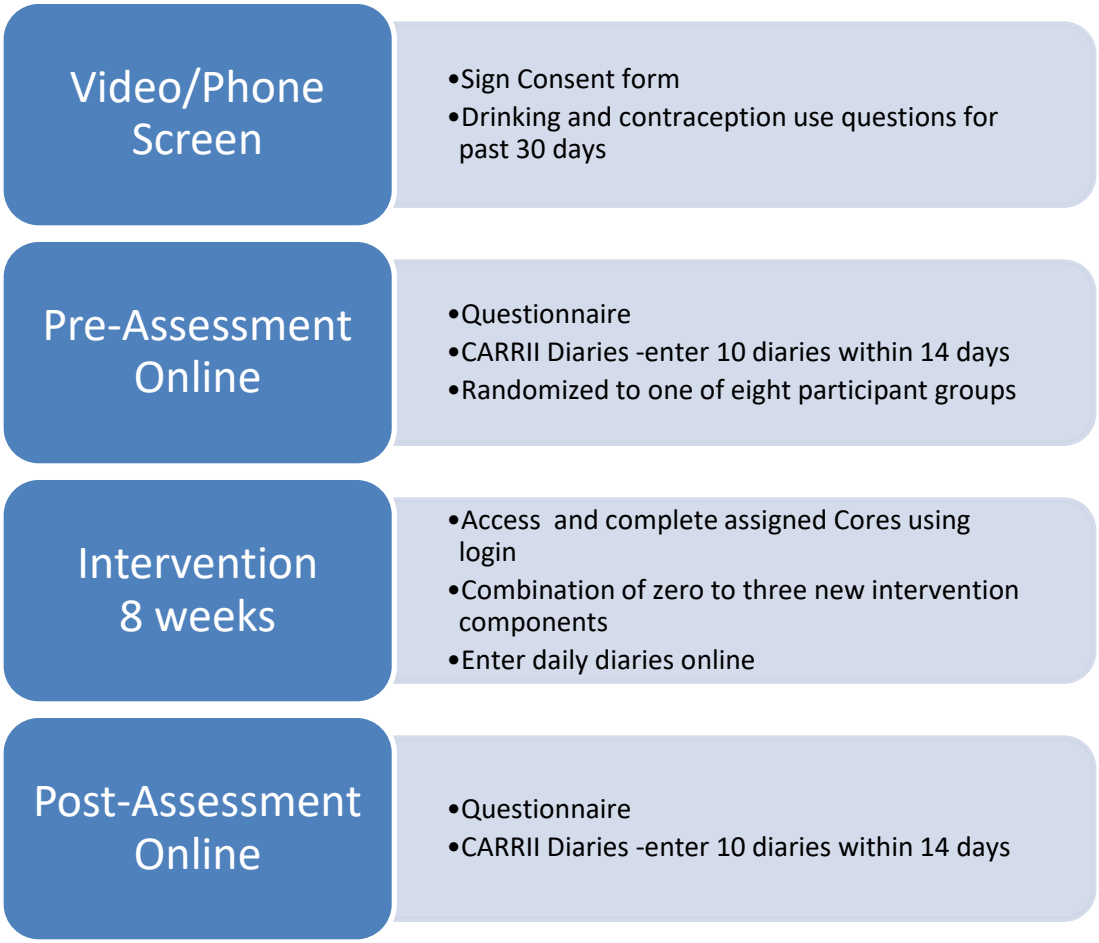
**Purpose of the research study:** The purpose of this study is to identify the best combination of new intervention components to use with CARRII, the first automated online intervention for alcohol-exposed pregnancies (AEP). This intervention is specifically designed for Native women and others who can become pregnant. Our goal is to maximize the effectiveness of the online intervention while keeping costs manageable 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 Americans.

**What you will do in the study:** Participants will test the CARRII Native online intervention, consisting of four Cores, over a 12-week period. Participants may also receive **up to three new intervention components**, along with the CARRII core intervention.

- You will participate in a **baseline interview**, which includes self-reported demographics questions, and a 30-day Timeline Follow-Back (TLFB) assessment of your alcohol and contraception use conducted over the phone, to determine your eligibility.
- You will complete an **online pre-treatment assessment**, including a survey that evaluates your knowledge about the risks of alcohol-exposed pregnancies (AEP).
- You will complete **14 days of online daily diaries** of alcohol use, vaginal sex, and contraception use.
- You will then be **randomized to one of 8 participant groups** and complete the **4 parts (Cores)** of the **CARRII Native internet intervention** over an 8-week period, as well as **online daily diaries** of alcohol use, vaginal sex, and contraception use.
- **After 3 months**, you will complete online questionnaires and 14 days of online daily diaries.
- You can skip any survey question, and you can stop the interview/survey at any time, if you are uncomfortable answering.

**Study Steps:**




The three **new components** that may be tested by yourself and other participants are:

1. Mailed pregnancy tests sent every 4 weeks.
2. Automated, personalized digital safer sex and drink counting/reduction skills training.
3. Fully automated **daily** text messaging, prompting usage of safer sex and drink reduction skills.

**Time required:** The study will require from six and a half (6.5) to eight and a half (8.5) hours of your time, based on the following:

The baseline phone call and online questionnaires will require about one and a half hours 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 1-month period will require a different amount of time, depending on which one you are randomized to:

- Monthly mailed pregnancy tests: 10 minutes
- Automated digital skills training: 1-2 hours

- Automated text messages: 60 minutes

The end-of-study questionnaires 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 providers and medical staff both on our team and in the communities where we will recruit participants, in the event the you experience any emotional or psychological discomfort.

Please initial to indicate that you have read and accept the following:

☐ You should not consider the information in the intervention to be a replacement of medical advice, but you should contact your gynecologist or other health care provider if you have further questions or concerns about contraception or pregnancy.

**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.

**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 assessments and 14 daily diaries, you will receive a $25 e-gift card. After completing the 3-month assessments and 14 daily diaries, you will receive a $125 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.**

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 # 7390

***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.