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

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Human Research Protection Program
Institutional Review Board for Social & Behavioral Sciences
iProtocol

Current User: **Park, Silvia (spp2d)**

Protocol Number: 6760

IRB of Record: UVA

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

Descriptive Title: CARRII Native Women

Previous IRB-SBS Protocol Number:

Date Approved: **2025-03-18**

This protocol record was electronically approved on 2025-03-19

This protocol record is currently Approved.

Personnel (UVA Only)

Principal Investigator: Ingersoll, Karen (kes7a) - Status: Faculty
Department: Department of Psychiatry and NB Sciences
Title: Professor
CITI Training:
2022-01-26 - Conflicts of Interest - Stage 1
2018-06-28 - Conflicts of Interest - Stage 1
2014-06-23 - Conflicts of Interest - Stage 1
2021-10-08 - Export Controls Course - Stage 1
2023-02-17 - GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
2022-12-07 - GCP for Social and Behavioral Research Best Practices for Clinical Research - Basic Course
2023-07-31 - IRB-HSR RESEARCHER BASIC COURSE
2020-08-28 - IRB-HSR RESEARCHER BASIC COURSE
2017-09-18 - IRB-HSR RESEARCHER BASIC COURSE
2023-07-31 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2020-08-28 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2017-09-18 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2021-10-08 - Undue Foreign Influence: Risks and Mitigations

Contact Person: Park, Silvia (spp2d)

Research Team (Sub-Investigators):

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Department: E0:MD-PSCH Psychiatry and NB Sciences
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CITI Training:
2024-11-21 - Conflicts of Interest - Stage 1
2020-09-08 - Conflicts of Interest - Stage 1
2016-08-30 - Conflicts of Interest - Stage 1
2025-03-03 - IRB-HSR RESEARCHER BASIC COURSE
2022-03-09 - IRB-HSR RESEARCHER BASIC COURSE
2019-01-29 - IRB-HSR RESEARCHER BASIC COURSE
2016-01-08 - IRB-HSR RESEARCHER BASIC COURSE
2025-03-03 - IRB-HSR RESEARCHER REFRESHER COURSE
2025-03-03 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2022-03-09 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2018-07-31 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS

2015-07-21 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2022-02-21 - Undue Foreign Influence: Risks and Mitigations

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Department: Department of Psychiatry and NB Sciences
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CITI Training:
2022-07-12 - GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
2023-02-16 - IRB-HSR RESEARCHER BASIC COURSE
2020-03-09 - IRB-HSR RESEARCHER BASIC COURSE
2017-03-21 - IRB-HSR RESEARCHER BASIC COURSE

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Title: No Data in UVa LDAP
CITI Training:
2023-01-14 - GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
2023-04-19 - IRB-HSR RESEARCHER BASIC COURSE
2020-03-12 - IRB-HSR RESEARCHER BASIC COURSE
2018-06-19 - IRB-HSR RESEARCHER BASIC COURSE
2017-03-13 - IRB-HSR RESEARCHER BASIC COURSE

Park, Silvia (spp2d)
Department: E0:MD-PSCH Psychiatry and NB Sciences
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CITI Training:
2023-12-15 - Conflicts of Interest - Stage 1
2019-02-04 - Conflicts of Interest - Stage 1
2023-09-26 - GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
2019-02-06 - GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
2019-02-04 - IRB-HSR RESEARCHER BASIC COURSE
2023-12-05 - IRB-HSR RESEARCHER REFRESHER COURSE
2023-12-06 - Social and Behavioral Responsible Conduct of Research

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CITI Training:
2023-01-03 - GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)
2023-01-04 - GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
2024-01-04 - IRB-HSR RESEARCHER BASIC COURSE
2021-02-03 - IRB-HSR RESEARCHER BASIC COURSE
2017-09-23 - IRB-HSR RESEARCHER BASIC COURSE
2022-12-09 - IRB-HSR RESEARCHER REFRESHER COURSE

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Title: Professor
CITI Training:
2022-06-27 - Conflicts of Interest - Stage 1
2018-06-16 - Conflicts of Interest - Stage 1
2014-07-15 - Conflicts of Interest - Stage 1
2023-02-18 - GCP FDA Refresher
2017-04-19 - GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
2019-05-07 - IRB-HSR RESEARCHER BASIC COURSE
2016-04-20 - IRB-HSR RESEARCHER BASIC COURSE
2022-05-27 - IRB-HSR RESEARCHER REFRESHER COURSE
2021-12-01 - Undue Foreign Influence: Risks and Mitigations

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Title: E0:Web Developer
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2023-01-09 - GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)

2024-01-02 - IRB-HSR RESEARCHER BASIC COURSE
2020-09-11 - IRB-HSR RESEARCHER BASIC COURSE
2017-08-26 - IRB-HSR RESEARCHER BASIC COURSE

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Title: E0:Senior Software Engineer
CITI Training:
2024-01-17 - GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
2024-06-26 - IRB-HSR RESEARCHER BASIC COURSE
2021-07-01 - IRB-HSR RESEARCHER BASIC COURSE
2024-08-12 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS
2021-07-01 - IRB-SBS RESEARCHER BASIC COURSE-NO PRISONERS

Department Chair: Clayton, Anita (ahc8v)

non-UVA Research Team (Sub-Investigators)

non-UVA Sub-Investigator: Darnell, Serea
Institution: Missouri Breaks Industries Research Inc.
Position at Institution: research study assistant
Email: Serea.Darnell@mbiri.com
Phone: (605) 791-1209
Training Documentation

View File: CITI_1_12September2024 SD CARRII1.pdf
date uploaded: 2024-12-04, by: Park, Silvia *(spp2d)*
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date approved: 2024-12-09

non-UVA Sub-Investigator: Dean, Kim
Institution: Missouri Breaks Industries Research Inc.
Position at Institution: Field Office Director
Email: kim.dean@mbiri.com
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Training Documentation

View File: Kim CITI 20241.pdf
date uploaded: 2024-12-04, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-12-09

non-UVA Sub-Investigator: Hanson, Jessica
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Training Documentation

View File: Hanson citiCompletionCertificate.pdf
date uploaded: 2024-05-16, by: Park, Silvia *(spp2d)*
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non-UVA Sub-Investigator: O'Leary, Marcia
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Training Documentation

View File: citiCompletionReport2025.pdf
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date approved: 2025-03-18

non-UVA Engaged Institutions (in the United States)

Use this section for non-UVA Institutions which are located in the United States.

Use the International Research section, farther down this page, for non-UVA Institutions located outside of the United States.

Is more than one institution located in the United States (another university, commercial institution, etc.) engaged in this research proposal? Yes

Institution Name: Missouri Breaks Industries Research Inc.

PI at Institution: O'Leary, Marcia - marcia.oleary@mbiri.com, 605-964-1260

IRB Contact at Institution: O'Leary, Marcia - marcia.oleary@mbiri.com, 605-964-1260

Institution Type: For profit institution

Institution Activities: The activities at this institution duplicate the activities at all of the other institutions involved in this study (including UVA).

Institution Review: This institution does not require IRB review for this protocol.

Institution Name: University of Minnesota Duluth

PI at Institution: Hanson, Jessica - jdhanson@d.umn.edu, 218-726-8783

IRB Contact at Institution: Allen, Andrew - relyIRB@umn.edu, 612-626-5654

Institution Type: US Postsecondary Institution

Institution Activities: The activities at this institution duplicate the activities at all of the other institutions involved in this study (including UVA).

Institution Review: This institution will rely on UVA to conduct an IRB review.

Study Overview

Anticipated end date for collecting data: 2025-06-30

Anticipated end date for analyzing data: 2025-08-31

Is this research funded? Yes

Funding Source(s): Federal government

Supply all Agency Grant Numbers & Titles currently associated with this protocol:

National Institutes of Health
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM
Award Number 5R61AA030581-02
Unique Federal Award Identification Number (FAIN) R61AA030581

Do any of the Funding Sources create a Conflict Of Interest for the Principal Investigator, Faculty Sponsor or Research Team (Sub-Investigators) listed on this protocol? No

What is the purpose in conducting this research? How does this study contribute to the advancement of knowledge and why is it worth doing?

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 (Native) women is higher, due to low contraception use and high binge drinking rates. For example, 20% of sexually active Native women in the Southwestern US are at risk for AEP, and 52% of pregnancies in the Navajo Nation are unplanned, compared to 45% nationally. Among Native pregnant women from Great Plains tribes, nearly 30% drink at binge levels and do not use birth control to prevent pregnancy. Among another sample of Native women from Great Plains tribes, 65% were sexually active, not seeking pregnancy, and not using birth control.

AEP can be prevented by avoiding an unintended pregnancy or reducing alcohol intake by those who may become pregnant. MPI Ingersoll was a PI on the seminal CHOICES study that developed the first efficacious theory-based AEP intervention, with 4 Motivational Interviewing (MI) counseling sessions. MPI Hanson adapted CHOICES for Native women in tribal communities. The

Native-adapted CHOICES reduced AEP risks among Native women, but was too costly to sustain for high-risk women and communities. In contrast, theory-based digital interventions are highly accessible, more convenient, scalable, and more sustainable, while still efficacious. In R34AA020853, Ingersoll piloted the first automated digital AEP intervention, CARRII. A nationwide pilot RCT showed that CARRII (but not the education control) significantly reduced AEP risk and pregnancy risk at 3 and 6 months, and drinking risk at 3 months.

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 this priority subgroup. Guided by the Multiphase Optimization Strategy (MOST), we will tailor CARRII's existing components for Native women and systematically test proposed novel components (derived from formative work with Native women), to develop an efficient and scalable intervention tailored to Native women at risk of AEP. Optimizing CARRII for Native women will require measuring the efficacy and costs of components to find a balance between impact and affordability for Native communities. The goal is to determine the optimal combination of novel intervention strategies to include with CARRII (tailored for Native women) that maximizes digital intervention efficacy at feasible cost for Native communities.

What will participants do in this study? Please provide an overall summary of the study plan. Where and when it will be conducted? What do you hope to learn from these activities? If the study has more than one phase, clearly map out the different phases. You will be required to describe the study components in more detail in later sections but use this paragraph to help your IRB reviewer to understand the general outline of the study. Other sections in the protocol form can be seen below.

For Aim 1 there are four study methods that will help the team evaluate and tailor CARRII intervention components for Native women and prepare for a trial. These iterative mixed methods formative studies include: a) develop an ongoing Native Partners Working Group to review study plans and findings over time with the research team, b) Quantitative surveys to estimate rate of AEP risk, interest/ ability to participate, health literacy, and other factors (n=300), c) Focus Groups to prototype and tailor new CARRII components (n=60), and d) Think-aloud User Testing (n=20) to finalize the CARRII intervention. The tailored CARRII core and its new components will be developed on a responsive design platform to permit use on any device.

Mixed methods research during Aim 1 will include 4 different components. They are: 1. Convene working group of Native American stakeholders. This will include indigenous women from the Southwestern region, urban Denver and the Mountain West region, where consultant Michelle Sarche is located and conducts Native health studies, and the Great Plains regions of Minnesota, South Dakota, and North Dakota where University of Minnesota-Duluth partner researcher Dr. Hanson is located and routinely recruits for her research. Indigenous women from the Mid-Atlantic may also be recruited, as UVA's indigenous representative, Kody Whistler, is connected to several tribes and groups of Native Americans residing in this region.

2. Collect data using a 35-minute survey of demographics, AEP risk, device use, recommendations for recruitment methods, and interest in subsequent trial with 300 Native women respondents, targeting approximately 100-150 per region (rural Great Northern Plains), urban Denver and rural mountain West and Southwest.

3. Conduct Iterative prototyping of existing and proposed CARRII components with 60 Native women across 10 Focus Group discussions. Content will be informed by Components 1 and 2.

4. Conduct User Testing of existing CARRII and candidate components with Think-Aloud methods among 20 Native women.

In Aim 2, we will Pilot test 5 new candidate components tailored to Native women at risk of AEP: After incorporating input from participants (SA 1) and the Native Partners Working Group, we will pilot candidate components to assess independent effects on AEP behavioral risk factors (drinking and contraception) while considering practical aspects such as frequency and duration of contact with participants, and costs of each component.

Participants will be Native women aged 18-44 with some drinking and some risk for pregnancy (some ineffective contraception use). Participants must have access to the Internet via a device they can access at least weekly. Each participant will complete a baseline survey including a telephone-administered 30-day Timeline follow-back of alcohol use and contraception use, to determine eligibility, and a short online survey evaluating knowledge about AEP risk, intentions and self-efficacy to change, and readiness to change alcohol and/or contraception behaviors.

They will then be randomized to receive one novel component condition, each of which is designed as an engaging experience that boosts motivation to continue participating, for a 6-week period. All participants will complete the 4 Cores of the CARRII Native internet intervention over the 6-week period alongside the novel component.

The candidates that will be tested are: 1) Telephone-administered 30-day timeline follow-back (TLFB) of drinking, sex, and contraception, administered by phone, of alcohol intake and contraception type by sexual encounter at enrollment and monthly (2 weeks after enrollment), which should increase awareness of AEP risk and motivation for alcohol and contraception behavior change, 2) Mailed pregnancy tests sent monthly to raise consciousness of pregnancy risk and to detect a new pregnancy early, which should increase motivation for contraception behavior change, 3) Automated, personalized digital safer sex and drink counting/reduction skills training, to improve drinking self-management skills and self-efficacy for drinking reduction and contraception use, 4) Fully automated text messaging prompting usage of safer sex and drink reduction skills, to prompt behavior change, which should increase self-efficacy for behavior change, and 5) Access to an anonymized Community Message Board of Native women to discuss challenges in behavior change, to give and receive social support, which should increase perceived social support for behavior change.

We plan interim phone calls after 3 weeks in the pilot trial to check on progress.

Participants will complete a second TLFB for the past 6 weeks for drinking and contraception behavior, and a short survey to rate the component they experienced, along with the System Usability Scale on their component, and measures of short-term knowledge, intentions to change, self-efficacy for change, and readiness to change alcohol use and contraception behaviors.

This Aim will determine preliminary effect sizes on alcohol and contraception use and costs of each new component. New components with the highest effect sizes in the 6-week pilot trials will be integrated with the tailored CARRII core intervention.

Is this study topic relevant to cancer risk factors, prevention, cancer treatment, or survivorship (e.g., pain, financial toxicity, etc.), or will the study purposefully include participants currently or previously diagnosed with cancer, or their caregivers?
No

(optional) **Study Overview file upload**: Below you have the option to upload additional files to help the Board better understand your study. You are not required to provide any additional explanation beyond completing the text boxes provided in this Study Overview section; however, for example, if you are using a new technology or a complicated process that would be more easily demonstrated with an image or video, you can upload the file here.

Study Overview
View File: contra_card_shortened_20240730.pdf
date uploaded: 2024-10-31, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-11-08

Study Overview
View File: drink_card_illustration_20240813.pdf
date uploaded: 2024-10-31, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-11-08

Study Overview
View File: HSR220448 LOS Missouri Breaks.pdf
date uploaded: 2024-09-04, by: Park, Silvia *(spp2d)*
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date approved: 2024-09-18

Study Overview
View File: SBS6760 Aim 2 CARRII Native push notifications.pdf
date uploaded: 2024-08-20, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-09-18

Study Overview
View File: SBS6760 Aim 2 CARRII Native Women Anonymous CMB Agreement 08.01.2024.docx
date uploaded: 2024-08-20, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-09-18

Study Overview
View File: SBS6760 Aim 2 How to Use a Pregnancy Test.docx
date uploaded: 2024-08-20, by: Park, Silvia *(spp2d)*

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date approved: 2024-09-18

Study Overview
View File: SBS6760 Aim 2 Novel Component CMB (1).docx
date uploaded: 2024-08-21, by: Park, Silvia *(spp2d)*
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date approved: 2024-09-18

Study Overview
View File: SBS6760 Aim 2 Novel Component Digital Skills.docx
date uploaded: 2024-08-20, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-09-18

Study Overview
View File: SBS6760 CARRII Native logos 11.04.24.docx
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This file is approved.
date approved: 2024-11-08

Participant Groups

Participant Group Name: Aim 1 Survey participants

Age Range (years): 18-44

Vulnerable populations: no vulnerable population (none)

Maximum number of participants, in this group, expected to enroll over the life of the study: 300

Minimum number of participants, in this group, expected to enroll over the life of the study: 1

Total number of participants, in this group, ever enrolled: 0

Approximate number of participants, in this group, currently enrolled: 0

Future Enrollment: We will enroll participants, in this group, during the next twelve months

Approximate number of participants, in this group, expected to enroll in the next twelve months: 300

Have participants, in this group, withdrawn from the study in the past year? No

Describe the participants in this group.

> Inclusion Criteria: participants must be between 18 and 44 years of age, sex assigned female at birth, and self-identify as Native American women.
>
> 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 this priority subgroup.

Will participants in this group be *compensated* for taking part in your study? Yes

Are any of the participants US citizens or US residents? Yes

This question applies only to participants who are US citizens or US residents.
Will participant payments be processed through an account administered by UVA? No

Describe your payment process, including information about the amount participants will be paid and how payment will be issued and delivered to participants.

> Participants will be paid $20 by e-gift card for survey completion.

Participant Group Name: Aim 2 Pilot Testing

Age Range (years): 18-44

Vulnerable populations: no vulnerable population (none)

Maximum number of participants, in this group, expected to enroll over the life of the study: 53

Minimum number of participants, in this group, expected to enroll over the life of the study: 1

Total number of participants, in this group, ever enrolled: 0

Approximate number of participants, in this group, currently enrolled: 0

Future Enrollment: We will enroll participants, in this group, during the next twelve months

Approximate number of participants, in this group, expected to enroll in the next twelve months: 53

Have participants, in this group, withdrawn from the study in the past year? No

Describe the participants in this group.

Inclusion Criteria: participants must self-identify as Native American women (or others who can become pregnant), and be between 18 and 44 years of age, with some drinking above risk levels and some risk for pregnancy (some ineffective contraception use). Participants must have access to the Internet via a device they can access at least weekly.

Exclusion criteria: unable to provide consent to participate due to significant cognitive problems or symptoms of a psychotic disorder.

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 this priority subgroup.

Will participants in this group be *compensated* **for taking part in your study?** Yes

Are any of the participants US citizens or US residents? Yes

This question applies only to participants who are US citizens or US residents.
Will participant payments be processed through an account administered by UVA? No

Describe your payment process, including information about the amount participants will be paid and how payment will be issued and delivered to participants.

The incentive for completing the Aim 2 Rapid Pilot Tests of one of the novel candidate intervention components is $100 total, provided as $25 for baseline survey and $75 for completing 6-week assessments. Participants will be paid by e-gift card.

Participant Group Name: Focus Group

Age Range (years): 18-44

Vulnerable populations: no vulnerable population (none)

Maximum number of participants, in this group, expected to enroll over the life of the study: 60

Minimum number of participants, in this group, expected to enroll over the life of the study: 1

Total number of participants, in this group, ever enrolled: 0

Approximate number of participants, in this group, currently enrolled: 0

Future Enrollment: We will enroll participants, in this group, during the next twelve months

Approximate number of participants, in this group, expected to enroll in the next twelve months: 60

Have participants, in this group, withdrawn from the study in the past year? No

Describe the participants in this group.

Inclusion Criteria: participants must self-identify as Native American women (or others who can become pregnant) and be between 18 and 44 years of age.

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 this priority subgroup.

Will participants in this group be *compensated* **for taking part in your study?** Yes

Are any of the participants US citizens or US residents? Yes

This question applies only to participants who are US citizens or US residents.
Will participant payments be processed through an account administered by UVA? No

Describe your payment process, including information about the amount participants will be paid and how payment will be issued and delivered to participants.

> Participants will be paid $50 by gift card, e-gift card, or check.

Participant Group Name: Think-Aloud

Age Range (years): 18-44

Vulnerable populations: no vulnerable population (none)

Maximum number of participants, in this group, expected to enroll over the life of the study: 20

Minimum number of participants, in this group, expected to enroll over the life of the study: 1

Total number of participants, in this group, ever enrolled: 0

Approximate number of participants, in this group, currently enrolled: 0

Future Enrollment: We will enroll participants, in this group, during the next twelve months

Approximate number of participants, in this group, expected to enroll in the next twelve months: 20

Have participants, in this group, withdrawn from the study in the past year? No

Describe the participants in this group.

> Inclusion Criteria: participants must self-identify as Native American women (or others who can become pregnant) and be between 18 and 44 years of age.
>
> 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 this priority subgroup.

Will participants in this group be *compensated* **for taking part in your study?** Yes

Are any of the participants US citizens or US residents? Yes

This question applies only to participants who are US citizens or US residents.
Will participant payments be processed through an account administered by UVA? No

Describe your payment process, including information about the amount participants will be paid and how payment will be issued and delivered to participants.

> Participants will be paid $50 by gift card, e-gift card, or check.

Participant Group Name: Working Group members

Age Range (years): 18-99

Vulnerable populations: no vulnerable population (none)

Maximum number of participants, in this group, expected to enroll over the life of the study: 8

Minimum number of participants, in this group, expected to enroll over the life of the study: 1

Total number of participants, in this group, ever enrolled: 0

Approximate number of participants, in this group, currently enrolled: 0

Future Enrollment: We will enroll participants, in this group, during the next twelve months

Approximate number of participants, in this group, expected to enroll in the next twelve months: 8

Have participants, in this group, withdrawn from the study in the past year? No

Describe the participants in this group.

Participants will be community partners. Participants must work or volunteer directly with Native Americans. This includes men and/or women who oversee health services, indigenous community leaders, and other volunteers who have expertise on Native women in their areas.

To ensure cultural appropriateness of this study, we will convene a working group of community partners to advise on best practices to conducting this study in the Native American communities.

Will participants in this group be *compensated* **for taking part in your study?** Yes

Are any of the participants US citizens or US residents? Yes

This question applies only to participants who are US citizens or US residents.
Will participant payments be processed through an account administered by UVA? No

Describe your payment process, including information about the amount participants will be paid and how payment will be issued and delivered to participants.

Participants will receive a $50 e-gift card for each working group meeting they attend. The maximum compensation for this component of the study is $250 dollars.

Participant Summary

Participant Group Name: Aim 1 Survey participants

Maximum number of participants, in this group, expected to enroll over the life of the study: 300

Participant Group Name: Aim 2 Pilot Testing

Maximum number of participants, in this group, expected to enroll over the life of the study: 53

Participant Group Name: Focus Group

Maximum number of participants, in this group, expected to enroll over the life of the study: 60

Participant Group Name: Think-Aloud

Maximum number of participants, in this group, expected to enroll over the life of the study: 20

Participant Group Name: Working Group members

Maximum number of participants, in this group, expected to enroll over the life of the study: 8

What special experience or knowledge does the Principal Investigator, Faculty Sponsor, and the Research Team (Sub-Investigators) have that will allow them to work productively and respectfully with the participants in this protocol and/or participant data?

Karen Ingersoll, Personal Statement:

I have two decades of experience as a behavioral scientist and NIH PI. I am a licensed clinical psychologist and tenured full professor at the University of Virginia School of Medicine. My research career focus is developing psychological interventions for people with intersecting medical and addictive disorders. I have been the PI on studies funded by the CDC, the AAMC, NIMH, NIDA, and NIAAA, and Co-I on studies funded by numerous other NIH institutes. My two research programs focus on different populations with intersecting medical and substance use behaviors. The first is women and alcohol, and my major research focus in this area is on testing interventions for alcohol-exposed pregnancy risk, with a goal of reducing Fetal Alcohol Spectrum Disorders. One of my significant research contributions is testing counseling interventions to reduce the risk of alcohol-exposed pregnancies. I was an original PI of the CHOICES intervention, a CDC funded project to develop and test the first preventive behavioral intervention for women with alcohol-exposed pregnancy risks. CHOICES which remains the most efficacious and disseminated counseling intervention in the world for AEP risk. I have adapted this intervention for American Indian (in collaboration with Dr. Hanson) and college women, and for scalable delivery via eHealth in CARRII (with Dr. Ritterband). My CHOICES collaborators and I published the first book on preventing alcohol-exposed pregnancies in 2015.

I have been an innovator in using technology to create and deliver efficacious brief behavioral interventions to reduce AEP Risk. Additionally, as a co-investigator, I have contributed to behavioral science research on digital interventions for diabetes, insomnia, heart disease, skin cancer, and others. My team adapted the CHOICES intervention for web delivery in the CARRII project funded by

an R34 from NIAAA. Some of this work is described in the publications below, and demonstrates my skills and experience to lead the proposed R61/R33 project. I have collaborated with MPIs Hanson and Tingey for 2 years to prepare for the proposed project, in which we will systematically tailor the CARRII intervention and pilot test novel intervention components using mixed methods preparatory work, followed by an optimization trial with Native women with AEP risk in a modern MOST factorial experiment.

Jessica Hanson, Personal Statement:

I am currently an Assistant Professor in the Department of Applied Human Sciences at the University of Minnesota Duluth, and I have worked with a number of American Indian communities for the past 15 years. As an expert on the prevention of alcohol-exposed pregnancies with preconceptional American Indian women, I was the Lead Evaluator on the Oglala Sioux Tribe (OST) CHOICES Program and worked with OST to successfully secure multiple NIH grants to expand and pilot test modified CHOICES interventions for use with American Indian women. This includes ongoing collaborations with tribal partners to conduct community needs assessments on preventing alcohol-exposed pregnancies with tribal communities; the development and implementation of Group CHOICES for American Indian women; and the development of the CHAT Program, or CHOICES for American Indian teens. The results of these efforts with the OST CHOICES Program have shown that the evidence-based CHOICES intervention—modified by and for the tribal communities as highlighted in several of my team's publications—can significantly reduce risk for alcohol-exposed pregnancies in preconceptional American Indian women. I am currently working as a Co-Investigator on a grant to implement a multi-site randomized control trial to further test CHOICES with American Indian women and to additionally evaluate the economic impact of an alcohol-exposed pregnancy prevention program for a reservation community.

About Community Partner Missouri Breaks Industries Research Inc.(MBIRI):
Missouri Breaks utilizes the Great Plains Institutional Review Board (GPIRB), and the GPIRB approval letter has been uploaded to the Permissions and Agreements section below.

"Missouri Breaks is a small Indian-owned business. Our main office is located on the Cheyenne River Sioux Reservation in South Dakota, and we have satellite offices on the Oglala Sioux Reservation (SD), Spirit Lake Nation (ND), and in Rapid City, SD. MBIRI is qualified under 25 USC 47 as a "Buy Indian" business to conduct research of medical problems and to disseminate information learned through this research to health care providers, tribal leaders, and community members."
Please see attached Letter of Support for the NIH proposal: HSR220448 LOS Missouri Breaks.pdf

What is the relationship between the participants of this study, and the Principal Investigator, Faculty Sponsor, and the Research Team (Sub-Investigators)? Does the Principal Investigator, Faculty Sponsor, or the Research Team (Sub-Investigators) know any of the participants personally or hold any position of authority over the participants (including but not limited to: grading authority, professional authority, etc.)? Do any of the researchers listed on the protocol stand to gain financially from any aspect of this research?

There is no relationship between the participants of this study, and the Principal Investigator, and the Research Team (Sub-Investigators).

No, the Principal Investigator, or the Research Team (Sub-Investigators) does not know any of the participants personally or hold any position of authority over the participants (including but not limited to: grading authority, professional authority, etc.).

No, none of the researchers listed on the protocol stand to gain financially from any aspect of this research.

Recruitment & Consent

How will participants be approached or contacted for recruitment into the study?

Working Group members: We have already convened the Working Group, who serve as key informants for the life of this study, via sister protocol HSR220448. We are closing HSR220448 and will re-consent those WG members to this protocol when we next convene a WG meeting.

We recruited from known community partner locations (U of Minnesota has done extensive work in the communities and has a strong working relationship with the tribal communities and health services in our study locations). We have focused our recruitment efforts on tribal communities in the Southwest, Rocky Mountains, Great Plains, and Great Lakes, and urban centers with large pockets of Natives, as well as those that are near tribal communities (e.g., Minneapolis, MN; Rapid City, SD; Denver, CO). Participants were be contacted by study team members to see if they would like to participate in the working group.

Survey participants: Flyers with inclusion criteria and study member's contact information, and Qualtrics pre-screening eligibility survey link, will be posted in local gathering areas and at community events. Social media advertisement will be utilized by study staff and partners, as well. Community partner Missouri Breaks will recruit participants for the Survey using these methods. The study will also utilize online recruitment services from third-party recruiter BuildClinical. BuildClinical will run an advertising campaign across relevant platforms and provide study staff with contact information for potential participants, who will be directed to the Qualtrics pre-

screening eligibility survey.

To address the issue of possible online recruitment-related fraud, we will conduct a background check once pre-screened, that uses name, address, phone number, and date of birth to confirm the information provided by the participant. Our study staff have access to a database owned by TransUnion, called TLOxp. This database will be used to search for applicants to ensure they are real people and meet basic criteria, such as age.
Potential participants will then be contacted by study members to review the consent for understanding (teach back method) and address any questions.

Focus Group Recruitment: 60 Native women participants ages 18 to 44 years of age, across up to 10 Focus Groups.

Think-Aloud Recruitment: We will recruit 20 Native women ages 18 and 44 years of age.

Women who have participated in the Survey component of Aim 1 are also eligible to participate in either or both of these components.

We are focusing our recruitment efforts on tribal communities in the Rocky Mountains, Great Plains, and Great Lakes, and urban centers with large pockets of Natives, as well as those that are near tribal communities (e.g., Minneapolis, MN; Rapid City, SD; Denver, CO). We will utilize methods proven for recruitment by partners including: 1) posting flyers at local gathering places and community events, 2) radio/print advertisements in local and regional outlets, 3) posting and paid advertisements on social media, 4) attending local events (e.g., health fairs, powwows) to administer surveys, and 5) working with community partners to provide information to patrons and refer participants to the study. Participants who express interest in the study will be provided information and, if interested, verbal consent will be obtained.

Community partner Missouri Breaks Industries Research Inc. (Missouri Breaks) will recruit participants for both the Focus Groups and Think-Alouds.

Aim 2 Recruitment: 53 Native women and others who can become pregnant, ages 18-44 years of age, considered near-eligible, with some drinking and some risk for pregnancy (some ineffective contraception use), and access to the Internet via a device they can access at least weekly (including up to 3 test users who are also near-eligible). Same as the above methods. Each of these methods will result in a potential participant completing a study interest form in Qualtrics. Study coordinator will utilize TransUnion's TLO Identity Check to verify they are a real person, are 18-44 years old, and female. Coordinator will send email to interested participants, to schedule the consenting process and Baseline phone call. The email will contain the study Drink card and Contraception card, in order to facilitate the 30-day TimeLine Follow-Back, which will determine eligibility.

Women who have participated in the Survey component of Aim 1, or the Think-Aloud or Focus Group Discussion, are also eligible to participate in Aim 2 if they meet the additional criteria. Past participants of any of those components who indicated interest in future participation may be contacted by the coordinator for recruitment to Aim 2. Participants in Aim 2 are also eligible to complete the Survey component.

Community partner Missouri Breaks Industries Research Inc. (Missouri Breaks) will also help recruit participants for Aim 2.

Do participants have any limitations on their ability to *consent* **?** No

Describe the limitations on their ability to consent:

What are the consent processes for this study?

Working Group members: Verbal consent will be obtained for participation, in person or via Zoom.

Survey participants: Potential participants will be contacted by study members to review the consent for understanding (teach back method) and address any questions. The remote e-Consent form will be emailed to the email address provided by the potential participant using DocuSign. Once informed consent has been obtained, a link to the Qualtrics survey will be sent to the subject via email.

Focus Group and Think-Aloud participants will be scheduled in a phone call with a coordinator or partner, to either a focus group session or think-aloud appointment in a local area, or online if in-person participation is not occurring at that time (due to the COVID-19 pandemic, or due to distance from a research center office). Participants who express interest in the study will be provided information and, if interested, verbal consent will be obtained. Community partner Missouri Breaks will consent participants for focus groups when these discussions are to be held in person at one of their locations.

For Aim 2, participants will be scheduled for a phone call with study coordinator, who will discuss the study procedures and review the informed consent, assessing participants' comprehension of the study, answering any questions that participants may have, and if interested, the eConsent form will be emailed to the participant to sign using DocuSign.

Are your participants either unable or unwilling to document their consent (i.e. sign a form)? No

Will participants be deceived and/or have information withheld from them about the study? No

Will participants be debriefed? No

Recruitment & Consent Tools

Consent or Assent (signature required)
View File: SBS6760 Aim 1 Survey Electronic Consent 12-05-24.docx
date uploaded: 2024-12-05, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-12-09

Consent or Assent (signature required)
View File: SBS6760 Aim 2 Electronic Informed Consent 12.05.24.docx
date uploaded: 2024-12-05, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-12-09

Consent or Notification (no signature required)
View File: SBS6760 Aim 1 FG TA Oral Consent 12-05-24.docx
date uploaded: 2024-12-05, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-12-09

Consent or Notification (no signature required)
View File: SBS6760 Aim 1 WG Telephone Recruitment Consent 12-04-2024.docx
date uploaded: 2024-12-05, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-12-09

Recruitment
View File: BCFS001189-UVA-Ingersoll-Survey [Landing Page].pdf
date uploaded: 2024-12-04, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-12-09

Recruitment
View File: BCFS001189-UVA-Ingersoll-Survey-Ad Copy.pdf
date uploaded: 2024-12-04, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-12-09

Recruitment
View File: BCFS001189-UVA-Ingersoll-Survey-Feed.pdf
date uploaded: 2024-12-04, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-12-09

Recruitment
View File: BCFS001189-UVA-Ingersoll-Survey-ScreeningForm.pdf
date uploaded: 2024-12-04, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-12-09

Recruitment
View File: BCFS001189-UVA-Ingersoll-Survey-Slides-Video1.pdf
date uploaded: 2024-12-04, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-12-09

Recruitment
View File: BCFS001189-UVA-Ingersoll-Survey-Slides-Video2.pdf
date uploaded: 2024-12-04, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-12-09

Recruitment
View File: SBS6760 Aim 2 Recruitment flyer 08.02.2024.docx
date uploaded: 2024-08-20, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-09-18

Recruitment
View File: SBS6760 CARRII Aim 1 FG TA Recruitment Flyer 05-17-24.doc
date uploaded: 2024-08-20, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-09-18

Recruitment
View File: SBS6760 CARRII Native Survey Recruitment flyer 11.19.24.docx
date uploaded: 2024-12-04, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-12-09

Recruitment
View File: SBS6760 Survey Telephone-Recruitment-Consent Script 12-04-2024.docx
date uploaded: 2024-12-04, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-12-09

Associate Recruitment & Consent Tools with Participant Groups

Participant Group Name: **Aim 1 Survey participants**
✓ Recruitment & Consent Tool: **SBS6760 Aim 1 Survey Electronic Consent 12-05-24.docx**
✓ Recruitment & Consent Tool: **BCFS001189-UVA-Ingersoll-Survey [Landing Page].pdf**
✓ Recruitment & Consent Tool: **BCFS001189-UVA-Ingersoll-Survey-Ad Copy.pdf**
✓ Recruitment & Consent Tool: **BCFS001189-UVA-Ingersoll-Survey-Feed.pdf**
✓ Recruitment & Consent Tool: **BCFS001189-UVA-Ingersoll-Survey-ScreeningForm.pdf**
✓ Recruitment & Consent Tool: **BCFS001189-UVA-Ingersoll-Survey-Slides-Video1.pdf**
✓ Recruitment & Consent Tool: **BCFS001189-UVA-Ingersoll-Survey-Slides-Video2.pdf**
✓ Recruitment & Consent Tool: **SBS6760 CARRII Native Survey Recruitment flyer 11.19.24.docx**
✓ Recruitment & Consent Tool: **SBS6760 Survey Telephone-Recruitment-Consent Script 12-04-2024.docx**

Participant Group Name: **Aim 2 Pilot Testing**
✓ Recruitment & Consent Tool: **SBS6760 Aim 2 Electronic Informed Consent 12.05.24.docx**
✓ Recruitment & Consent Tool: **SBS6760 Aim 2 Recruitment flyer 08.02.2024.docx**

Participant Group Name: **Focus Group**
✓ Recruitment & Consent Tool: **SBS6760 Aim 1 FG TA Oral Consent 12-05-24.docx**
✓ Recruitment & Consent Tool: **SBS6760 CARRII Aim 1 FG TA Recruitment Flyer 05-17-24.doc**

Participant Group Name: **Think-Aloud**
✓ Recruitment & Consent Tool: **SBS6760 Aim 1 FG TA Oral Consent 12-05-24.docx**
✓ Recruitment & Consent Tool: **SBS6760 CARRII Aim 1 FG TA Recruitment Flyer 05-17-24.doc**

Participant Group Name: **Working Group members**
✓ Recruitment & Consent Tool: **SBS6760 Aim 1 WG Telephone Recruitment Consent 12-04-2024.docx**

Data Sources

Data Source Name: Aim 1 Survey

When will the data be collected? Some data are collected but new data may be added to the data set after IRB-SBS approval of this protocol.

Who will collect the data? Primary data source

Describe this Data Source.

The Survey includes items to characterize demographics, parity, literacy levels, AEP risk, drinking levels, knowledge of FASD, location, Tribal affiliation, cultural preferences for tailoring, preferred digital platforms, methods of access to mobile devices/Internet, and interest in a digital women's health study about alcohol and birth control.

Some survey data was collected under sister protocol HSR220448. That protocol will be closed, and that data will be analyzed together with data collected from SBS6760.

Will a recording device (e.g. audio, video, photographic) be used to collect data/materials from participants? No

Are the participant's identifying information included as part of the data at any time? No

How will you receive the data so that the data are not linked to identifying information?

Data Collection: Data from this Survey will be collected in Qualtrics, which is a secure data management system used by the Research Team for many of our studies. Fraud prevention steps will be utilized, including reCAPTCHA, and creating embedded data points (e.g. IP Address, latitude and longitude, browser type, and browser version). Several unique URLs will be created for distribution of the screening questions survey, to aid in detection of fraudulent activity, as well.

Data Management: Data that is extracted from survey software will be stored on secure UVA servers. Only the study team will have access to these servers. Any data that is shared outside of survey software will be de-identified using only study ID numbers and not names.

We will use descriptive statistics to determine the rate of women who are eligible for CARRII, interested in CARRII, and their demographic and digital access characteristics. All analyses and reports created from the study data analysis will only include aggregate statistical summaries. Standard procedures for addressing requests to access the limited dataset for analysis will be reviewed for scientific merit, feasibility, and study design. External investigators will only be allowed access to the data when collaborating with one of the internal investigators. Results of these 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 violate participant confidentiality.

Data Source Name: Aim 1 Survey prescreening questionnaire

When will the data be collected? Some data are collected but new data may be added to the data set after IRB-SBS approval of this protocol.

Who will collect the data? Primary data source

Describe this Data Source.

The prescreening questionnaire includes items to determine eligibility and characterize demographics.

Some prescreening questionnaire data was collected under sister protocol HSR220448. That protocol will be closed, and that data will be analyzed together with data collected from SBS6760.

Will a recording device (e.g. audio, video, photographic) be used to collect data/materials from participants? No

Are the participant's identifying information included as part of the data at any time? No

How will you receive the data so that the data are not linked to identifying information?

Data Collection: Data from this prescreening questionnaire will be collected in Qualtrics, which is a secure data management system used by the Research Team for many of our studies. Fraud prevention steps will be utilized, including reCAPTCHA, and creating embedded data points (e.g. IP Address, latitude and longitude, browser type, and browser version). Several unique URLs will be created for distribution of the screening questions survey, to aid in detection of fraudulent activity, as well.

Data Management: Data that is extracted from Qualtrics survey software will be stored on secure UVA servers. Only the study team will have access to these servers. Any data that is shared outside of survey software will be de-identified using only study ID numbers and not names.

We will use descriptive statistics to determine the rate of women who are eligible for CARRII, interested in CARRII, and their demographic and digital access characteristics. All analyses and reports created from the study data analysis will only include aggregate statistical summaries. Standard procedures for addressing requests to access the limited dataset for analysis will be reviewed for scientific merit, feasibility, and study design. External investigators will only be allowed access to the data when collaborating with one of the internal investigators. Results of these 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 violate participant confidentiality.

Data Source Name: Aim 2 Baseline Survey

When will the data be collected? Data will be collected after IRB-SBS approval of this protocol.

Who will collect the data? Primary data source

Describe this Data Source.

Each participant will complete a short online survey evaluating knowledge about AEP risk, intentions and self-efficacy to change, and readiness to change alcohol and/or contraception behaviors, to include the following instruments:
SBS6760 Aim 2 Approved Importance, Confidence, Readiness Scale
SBS6760 Aim 2 URICA-CARRII Native

Will a recording device (e.g. audio, video, photographic) be used to collect data/materials from participants? No

Are the participant's identifying information included as part of the data at any time? No

How will you receive the data so that the data are not linked to identifying information?

Study staff will administer the survey over the phone and collect responses either on paper first, using Study ID number only, and then transferring data to a digital file stored on secure Z Drive (\\hscs-share2), or collect responses directly to a digital file stored on the Z Drive.

Personally identifying information (PII) will be stored separately from study data, which will be recorded by primary unique Study ID number only, to maintain anonymity.

Data Source Name: Aim 2 CARRII Native Interest Form

When will the data be collected? Data will be collected after IRB-SBS approval of this protocol.

Who will collect the data? Primary data source

Describe this Data Source.

This form will be used for pre-screening participants to ensure they meet the eligibility criteria based on alcohol consumption and use of contraception.

Will a recording device (e.g. audio, video, photographic) be used to collect data/materials from participants? No

Are the participant's identifying information included as part of the data at any time? Yes, and participant identifiers will NOT be retained

What identifiers will be connected to the data and will you have access to those identifiers?

Name, address, DOB, sex, phone number, email address will be collected via Qualtrics survey.

Describe the process for stripping participant identifiers from the data.

Participants who are enrolled will be assigned a study ID. De-identified responses will be saved to a file stored on secure Z Drive (\\hscs-share2).

Personally identifying information (PII) will be stored separately from study data, which will be recorded by primary unique Study ID number only, to maintain anonymity.

Data Source Name: Aim 2 Demographics and 30-day TLFB for eligibility

When will the data be collected? Data will be collected after IRB-SBS approval of this protocol.

Who will collect the data? Primary data source

Describe this Data Source.

Each participant, after consenting, will complete a demographics questionnaire online via Qualtrics, and then be interviewed by the coordinator, to complete a 30-day TLFB to determine eligibility. This will include the following instruments:

SBS6760 CARRII Aim 2 demographics ver 10.31.24
SBS6760 CARRII_90 Day_TLFB_combined_10.31.2024

Will a recording device (e.g. audio, video, photographic) be used to collect data/materials from participants? No

Are the participant's identifying information included as part of the data at any time? No

How will you receive the data so that the data are not linked to identifying information?

Study staff will administer the demographics questionnaire online via Qualtrics.
The 30-day TLFB is conducted over the phone and the responses collected either on paper first, using Study ID number only, and then transferring data to a digital file stored on secure Z Drive (\\hscs-share2), or directly to a digital file stored on the Z Drive.

Personally identifying information (PII) will be stored separately from study data, which will be recorded by primary unique Study ID number only, to maintain anonymity.

Data Source Name: Aim 2 Past Month TLFB

When will the data be collected? Data will be collected after IRB-SBS approval of this protocol.

Who will collect the data? Primary data source

Describe this Data Source.

Telephone-administered 30-day timeline follow-back (TLFB) of drinking, sex, and contraception, administered by phone, of alcohol intake and contraception type by sexual encounter.

Will a recording device (e.g. audio, video, photographic) be used to collect data/materials from participants? No

Are the participant's identifying information included as part of the data at any time? No

How will you receive the data so that the data are not linked to identifying information?

Study staff will administer the survey over the phone and collect responses on paper first, using Study ID number only, and then transferring data to a digital file stored on secure Z Drive (\\hscs-share2).

Personally identifying information (PII) will be stored separately from study data, which will be recorded by primary unique Study ID number only, to maintain anonymity.

Data Source Name: Aim 2 Post 6-Week Surveys and 6-week TLFB

When will the data be collected? Data will be collected after IRB-SBS approval of this protocol.

Who will collect the data? Primary data source

Describe this Data Source.

Participants will complete a short survey to rate the component they experienced, along with the System Usability Scale on their component, and measures of short-term knowledge, intentions to change, self-efficacy for change, and readiness to change alcohol use and contraception behaviors, to include the instruments listed for Baseline, as well as:
SBS6760 Aim 2 Internet-Evaluation-and-Utility-Questionnaire
SBS6760 Aim 2 Internet-Impact-and-Effectiveness-Questionnaire
Coordinator will conduct 6-week TLFB over the phone, utilizing the same methods as for the eligibility TLFB.

Will a recording device (e.g. audio, video, photographic) be used to collect data/materials from participants? No

Are the participant's identifying information included as part of the data at any time? No

How will you receive the data so that the data are not linked to identifying information?

Study staff will administer the survey over the phone and collect responses either on paper first, using Study ID number only, and then transferring data to a digital file stored on secure Z Drive (\\hscs-share2), or collect responses directly to a digital file stored on

the Z Drive.

Personally identifying information (PII) will be stored separately from study data, which will be recorded by primary unique Study ID number only, to maintain anonymity.

Data Source Name: Focus Group Discussion Questions

When will the data be collected? Data will be collected after IRB-SBS approval of this protocol.

Who will collect the data? Primary data source

Describe this Data Source.

Focus groups will be conducted in person or remotely. Community partner Missouri Breaks will conduct some focus group discussions in person at their locations.

Participants will complete a consent and a short demographic survey. We will conduct up to 10 focus group discussions (FGD) that are organized based on Tribal and geographic region. Each FGD will consist of up to 6 participants, will last up to 2 hours and will be facilitated by a trained study staff member and one investigator.

During the FGD, participants will discuss acceptability, likeability, usability, comprehension and cultural acceptability of: 1) a timeline follow-back for both alcohol and contraception (see attached file); 2) monthly pregnancy tests and if they would raise the consciousness of pregnancy risk and increase motivation for contraception behavior change; 3) automated, personalized digital safer sex and drink counting/reduction skills training; 4) automated text messaging on safer sex and drink reduction skills; and 5) an anonymized Community Message Board of Native women to discuss challenges in behavior change.

Participants will receive a $50 gift card, e-gift card, or check, for their participation.

Will a recording device (e.g. audio, video, photographic) be used to collect data/materials from participants? Yes

What type(s) of recording device(s) will be used in this data tool? Audio

Describe each recording device(s) and provide a justification for using the recording device.

FGDs will be audio-recorded and transcribed. We will use Zoom to audio record (NOT video record) the remote sessions.

Transcripts will be analyzed using qualitative analysis software. Analytic memos will be generated to document initial impressions of themes. Transcripts will be assigned codes based on the transtheoretical model and emergent themes.

Are the participant's identifying information included as part of the data at any time? No

How will you receive the data so that the data are not linked to identifying information?

All names will be redacted from transcripts, along with other information that might disclose the person’s identity.

Data Source Name: Think-Aloud Interview Instructions

When will the data be collected? Data will be collected after IRB-SBS approval of this protocol.

Who will collect the data? Primary data source

Describe this Data Source.

Think-Alouds will be conducted as follows: 1) women use the intervention components on personal devices (see attached files describing Cores 1-4), and 2) narrate their reactions and thoughts, including how to navigate, and what they expect to see on each page and section of the intervention. Observing their use, including clicks, pauses, and navigation will be done remotely with usability testing websites on a conference calling platform, or can be conducted in person at a site convenient to participants.

Will a recording device (e.g. audio, video, photographic) be used to collect data/materials from participants? Yes

What type(s) of recording device(s) will be used in this data tool? Audio Video

Describe each recording device(s) and provide a justification for using the recording device.

Think-Aloud interviews will be audio and video-recorded and transcribed. We will use Zoom to audio and video record the remote sessions.

Analytic memos will be generated to document initial impressions of themes. Results will guide the revision of content and look/feel.

Are the participant's identifying information included as part of the data at any time? No

How will you receive the data so that the data are not linked to identifying information?

All names will be redacted from transcripts, along with other information that might disclose the person's identity.

Data Source Name: Working Group meeting

When will the data be collected? Some data are collected but new data may be added to the data set after IRB-SBS approval of this protocol.

Who will collect the data? Primary data source

Describe this Data Source.

The working group will be convened as needed. The working group will occur over the first and second years of the study. During these meetings we will ask working group members for their insight in best practices for recruitment within the Native American communities and way to ensure the study is conducted in a culturally sensitive and appropriate manner.

Working Group Analysis: Meeting minutes will be recorded (via typing/handwriting) and reviewed via rapid qualitative analysis to find emerging themes.

Will a recording device (e.g. audio, video, photographic) be used to collect data/materials from participants? No

Are the participant's identifying information included as part of the data at any time? No

How will you receive the data so that the data are not linked to identifying information?

De-identified notes from meetings will be stored on Box.

Associate Data Sources with Data Sources

If you are you linking the participants in a data set with their content in a different data set, use this section to associate and describe the linked Data Sources.

Data Source Name: **Aim 1 Survey**
✓ Data Source Name: **Aim 1 Survey prescreening questionnaire**

Data Source Name: **Aim 1 Survey prescreening questionnaire**
✓ Data Source Name: **Aim 1 Survey**

Data Source Name: **Aim 2 Baseline Survey**
✓ Data Source Name: **Aim 2 CARRII Native Interest Form**
✓ Data Source Name: **Aim 2 Demographics and 30-day TLFB for eligibility**
✓ Data Source Name: **Aim 2 Past Month TLFB**
✓ Data Source Name: **Aim 2 Post 6-Week Surveys and 6-week TLFB**

Data Source Name: **Aim 2 CARRII Native Interest Form**
✓ Data Source Name: **Aim 2 Baseline Survey**
✓ Data Source Name: **Aim 2 Demographics and 30-day TLFB for eligibility**
✓ Data Source Name: **Aim 2 Past Month TLFB**
✓ Data Source Name: **Aim 2 Post 6-Week Surveys and 6-week TLFB**

Data Source Name: **Aim 2 Demographics and 30-day TLFB for eligibility**
✓ Data Source Name: **Aim 2 Baseline Survey**
✓ Data Source Name: **Aim 2 CARRII Native Interest Form**
✓ Data Source Name: **Aim 2 Past Month TLFB**
✓ Data Source Name: **Aim 2 Post 6-Week Surveys and 6-week TLFB**

Data Source Name: **Aim 2 Past Month TLFB**
✓ Data Source Name: **Aim 2 Baseline Survey**
✓ Data Source Name: **Aim 2 CARRII Native Interest Form**
✓ Data Source Name: **Aim 2 Demographics and 30-day TLFB for eligibility**
✓ Data Source Name: **Aim 2 Post 6-Week Surveys and 6-week TLFB**

Data Source Name: **Aim 2 Post 6-Week Surveys and 6-week TLFB**
✓ Data Source Name: **Aim 2 Baseline Survey**
✓ Data Source Name: **Aim 2 CARRII Native Interest Form**
✓ Data Source Name: **Aim 2 Demographics and 30-day TLFB for eligibility**
✓ Data Source Name: **Aim 2 Past Month TLFB**

Data Source Name: **Focus Group Discussion Questions**
(not associated with other Data Source)

Data Source Name: **Think-Aloud Interview Instructions**
(not associated with other Data Source)

Data Source Name: **Working Group meeting**
(not associated with other Data Source)

Describe the processes for linking the data:

Aim 1 prescreening data will be matched with Survey data and combined based on Study ID number.

In Aim 2, each participant will complete:
--a telephone-administered 30-day month Timeline follow-back of alcohol use and contraception use, and 2 baseline surveys including:
--a short online survey evaluating knowledge about AEP risk, intentions and self-efficacy to change, and
--readiness to change alcohol and/or contraception behaviors.

All Aim 2 participants will also complete:
--a second TLFB for the past 6 weeks for drinking and contraception behavior, and
--a short survey to rate the component they experienced, along with
--the System Usability Scale on their component, and
--repeat the 2 baseline surveys.

Aim 2 participants who are randomized to the 30-day TLFB component will complete an additional telephone-administered past month Timeline follow-back four weeks after enrollment.

Data will be recorded by primary unique Study ID number.

Associate Data Sources with Participant Groups

Participant Group Name: **Aim 1 Survey participants**
✓ Data Source Name: **Aim 1 Survey**
✓ Data Source Name: **Aim 1 Survey prescreening questionnaire**

Participant Group Name: **Aim 2 Pilot Testing**
✓ Data Source Name: **Aim 2 Baseline Survey**
✓ Data Source Name: **Aim 2 CARRII Native Interest Form**
✓ Data Source Name: **Aim 2 Demographics and 30-day TLFB for eligibility**
✓ Data Source Name: **Aim 2 Past Month TLFB**
✓ Data Source Name: **Aim 2 Post 6-Week Surveys and 6-week TLFB**

Participant Group Name: **Focus Group**
✓ Data Source Name: **Focus Group Discussion Questions**

Participant Group Name: **Think-Aloud**
✓ Data Source Name: **Think-Aloud Interview Instructions**

Participant Group Name: **Working Group members**
✓ Data Source Name: **Working Group meeting**

Data Sources Upload

Instrument
View File: CARRII Native Focus Group Materials 06-27-24.pptx
date uploaded: 2024-06-28, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-07-02

Instrument
View File: CARRII Native in Rise Core 1 webflow rev 06-27-24.docx
date uploaded: 2024-06-28, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-07-02

Instrument
View File: CARRII Native in Rise Core 2 Contraception webflow Rev. 06-27-24.docx
date uploaded: 2024-06-28, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-07-02

Instrument
View File: CARRII Native in Rise Core 3 Drinking webflow Rev. 06-27-24.docx
date uploaded: 2024-06-28, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-07-02

Instrument
View File: CARRII Native in Rise Core 4 Wrap Up webflow Rev. 06-27-24.docx
date uploaded: 2024-06-28, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-07-02

Instrument
View File: Look and feel for Native American women.docx
date uploaded: 2024-06-14, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-06-14

Instrument
View File: SBS6760 Aim 2 Approved Importance, Confidence, Readiness Scale.docx
date uploaded: 2024-08-20, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-09-18

Instrument
View File: SBS6760 Aim 2 CARRII Native Interest Form 02.18.2025.docx
date uploaded: 2025-02-18, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2025-02-24

Instrument
View File: SBS6760 Aim 2 CARRII TLFB_combined_07.31.2024.doc
date uploaded: 2024-08-20, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-09-18

Instrument
View File: SBS6760 Aim 2 Internet-Evaluation-and-Utility-Questionnaire.docx
date uploaded: 2024-08-20, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-09-18

Instrument
View File: SBS6760 Aim 2 Internet-Impact-and-Effectiveness-Questionnaire.docx
date uploaded: 2024-08-20, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-09-18

Instrument
View File: SBS6760 Aim 2 URICA-CARRII Native.docx
date uploaded: 2024-08-20, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-09-18

Instrument
View File: SBS6760 CARRII Aim 2 demographics ver 10.31.24.docx
date uploaded: 2024-10-31, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-11-08

Instrument
View File: SBS6760 CARRII Native Focus group questions 06-27-24 CLEAN.docx
date uploaded: 2024-08-20, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-09-18

Instrument
View File: SBS6760 CARRII Native Think Aloud Instructions 05-17-24.docx
date uploaded: 2024-08-20, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-09-18

Instrument
View File: SBS6760 CARRII_90 Day_TLFB_combined_10.31.2024.doc
date uploaded: 2024-10-31, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-11-08

Instrument
View File: SBS6760 CARRII_TLFB_combined_03-07-2024.pdf
date uploaded: 2024-06-28, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-07-02

Instrument
View File: SBS6760 Sample Working Group Outline 12-04-2024.docx
date uploaded: 2024-12-04, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-12-09

Instrument
View File: SBS6760_CARRII Native Aim 1 Prescreening Questionnaire 11.19.24.docx
date uploaded: 2024-12-04, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-12-09

Instrument
View File: SBS6760_CARRII Native Aim 1 Survey 11.19.24.docx
date uploaded: 2024-12-04, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-12-09

Permission to Access Data Source and Participant Group

Are there any rules or restrictions to access Data Sources and/or Participant Groups? No

Permissions and/or Agreements

Proof of Permission
View File: CITI_1 12September2024 SD CARRII.pdf
date uploaded: 2024-09-12, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-09-18

Proof of Permission
View File: CITI_2 12September2024 SD CARRII.pdf

date uploaded: 2024-09-12, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-09-18

Proof of Permission
View File: CITI_3 12September2024 SD CARRII.pdf
date uploaded: 2024-09-12, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-09-18

Proof of Permission
View File: GPIRB Approval_Aim 1 Data Collection MBIRI.pdf
date uploaded: 2024-09-09, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-09-18

Proof of Permission
View File: Kim CITI 2024.pdf
date uploaded: 2024-09-16, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-09-18

Proof of Permission
View File: Kim Citi GCP 1.pdf
date uploaded: 2024-09-16, by: Park, Silvia *(spp2d)*
This file is approved.
date approved: 2024-09-18

Reliance Agreement - non-UVA Institution - Signed IAA
View File: 6760_U_of_M_SMART_IRB_Letter_of_Acknowledgement_UVA_IRB_of_Record_FINAL.pdf
date uploaded: 2025-01-07, by: Monroe, Jeff *(mjm6ny)*
This file is approved.
date approved: 2025-01-07

Data Reports & Storage

How will data/materials be stored? What measures will be taken to secure these data during collection and analysis? If the data includes recordings, what will be done with the recordings (including if/when the recordings will be destroyed)? Describe the long-term plan for maintaining the data when the active research phase is completed. Please note that you may need additional "material release" consent forms if you are using recordings for purposes beyond the study.

Aim 1 Working Group: All notes and meeting minutes will be stored on UVA secure servers (Z:drive or Box). External investigators will be allowed access to de-identified notes via secure Box login.

Aim 1 Survey, including prescreening questionnaire: Data that is extracted from Qualtrics survey software will be stored on secure UVA servers. Only the study team will have access to these servers. Any data that is shared outside of survey software will be de-identified using only study ID numbers and not names. External investigators will be allowed access to de-identified data via secure Box login.

Aim 1 FGD and T-A Data Collection: FGDs will be audio-recorded and transcribed. We will use Zoom to audio record (NOT video record) the remote sessions. The T-As will be audio and video recorded and transcribed.

Aim 1 FGD and T-A Data Management: Immediately after the sessions, the audio and video recordings will be stored on the Z: drive (\\hscs-share2). All names will be redacted from transcripts, along with other information that might disclose the person’s identity.

The audio and video recordings will be kept for up to three years after the study has ended. After that time, they will be destroyed/deleted.

Aim 2 data will be recorded to a file stored on the secure Z: drive (\\hscs-share2).

Aim 2 participants randomized to the automated text messaging component will be sent text messages via third-party vendor Textla https://www.textla.com/. Data security advised us, ""This review has been rejected as the data types you mentioned do not need a review at this time. You can proceed with implementing the vendor's product because no further review is required." The study coordinator will utilize the Textla platform to enter phone numbers only for those participants.

How will data/materials be reported for this study? Will the results be reported in aggregate or will individual data be discussed?

The study researchers may use an AI program, like Copilot or Chat GPT, for transcription services for Aim 1 and Aim 2.

Aim 1:
Survey Data Analysis: We will use descriptive statistics to determine the rate of women who are eligible for CARRII, interested in CARRII, and their demographic and digital access characteristics. All analyses and reports created from the study data analysis will only include aggregate statistical summaries. Standard procedures for addressing requests to access the limited dataset for analysis will be reviewed for scientific merit, feasibility, and study design. External investigators will be allowed access to de-identified data via data uploaded to NIAAA's data archive, or when collaborating with one of the internal investigators. Results of these 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 violate participant confidentiality.

Focus Group Analysis: FGDs will be audio-recorded and transcribed. Transcripts will be analyzed using qualitative analysis software. Analytic memos will be generated to document initial impressions of themes. Transcripts will be assigned codes based on TTM and emergent themes.

Statistical Power: This is a qualitative study and while traditional statistical power is not relevant, we will assess inter-coder reliability throughout this process and use team-based review and consensus and a grid to determine when data saturation is reached. Results will reveal the acceptability, likeability, usability, comprehension of, and cultural acceptability of each novel candidate by Native women. Results will further guide the team on right-sizing the intervention's volume, density of material, style, and cultural tailoring, as well as most-preferred and accessible platforms (smartphone, computer, tablet, etc.)

Think-Aloud Analysis: Data from Think-aloud testing will be audio and video-recorded and transcribed. Transcripts will be analyzed using qualitative analysis software. Analytic memos will be generated to document initial impressions of themes. Transcripts will be coded based on TTM constructs or emergent themes. We will assess inter-coder reliability throughout this process and use team-based consensus to determine when data saturation is reached. Results will guide the revision of content and look/feel.

Statistical Power: This is a qualitative study and while traditional statistical power is not relevant, we will assess inter-coder reliability throughout this process and use team-based review and consensus and a grid to determine when data saturation is reached. Results will reveal how users navigate online intervention components and what they miss or skip when using them. This information is crucial to designing a final version of novel components so that it is easily usable, understood, and impactful.

Aim 2:
Researchers may use AI to analyze de-identified data for Aim 2. This AI program may store data outside of UVA for future use.

Primary Outcomes: The rapid pilot tests in Aim 2 will assess changes from baseline to 6 weeks in knowledge about drinking and contraception, intention to change, self-efficacy for change, and readiness for change. The primary outcomes are differences in drinking and contraception behaviors from baseline to 6-weeks on the TLFB.

Hypotheses: The hypothesis is that some (and possibly all) of the piloted components will show effects on knowledge, intention to change, self -efficacy to change, and readiness to change. Additionally, we hypothesize that at least 2 of the piloted components will show significant change from baseline to 6 weeks on alcohol intake and contraception use.

Analysis: We will calculate baseline to 6-week improvements in knowledge about drinking and contraception, intention to change, self-efficacy for change, and readiness for change, and will calculate differences in drinking and contraception behaviors from baseline to 6-week on the TLFB. Intervention cost data (study budget, expense reports and labor costs) will be estimated using time-driven activity-based costing. We will calculate effect sizes of each component to identify those with the strongest effects on drinking and contraception for inclusion in the factorial experiment in Aim 3. The focus of this aim is to determine the effect size of each novel component, which is currently unknown. These findings will then inform the power for Aim 3.

If a participant decides to withdraw from the study, how will you handle their data?

We will keep/analyze data previously collected, but will stop collecting new data once a participant withdraws.

Do you plan to publish your raw data after the study is completed *(i.e. open-access or open source publishing)*? Yes

Will other parties (i.e. other corporations, institutions, researchers) have access to or retain a copy of the data? Yes

International Research

Risks & Benefits

Is loss of confidentiality and/or privacy a risk to participants? Yes

What will be done to protect participants from loss of confidentiality and/or privacy?

All data will be collected explicitly and exclusively for this study and will be maintained following HIPAA regulations. Data collected through the Internet will be obtained through secured means and stored on secure Z Drive (\\hscs-share2). Personal Health Information (PHI) will be stored separately from study data, which will be recorded by primary unique ID number only to maintain anonymity. Other than the email address and phone number of the subject, no PHI will be utilized in automated email and/or text message prompts associated with the online interventions. The email addresses and phone numbers, however, will be stored only on our Z Drive (\\hscs-share2).

Risk of inadvertent disclosure of sexual or drinking behaviors is highly unlikely but this very remote risk will be disclosed to participants during the consent process.

Describe any remaining potential risks to participants. For example, are any of your participants or participant groups "risk-sensitive"? Include information about the probability of harm (i.e. how likely it is that harm will occur). What will be done to reduce risk to participants? If something unexpected involving risk happens, how will you handle it?

Only members of the study team will hear the sessions. We will summarize participant's answers to help us improve the study, or to describe study findings, but all personally identifying information will be removed. No one outside the study team will hear audio recordings.

Are there direct benefits to the participants in this study? Yes

Describe the overall benefit of this study and the direct benefits to the participants.

For Aim 2: There are potential benefits to participants, such as an increased understanding of the importance of reducing AEP risk, improving contraception habits, or reducing drinking, which could reduce morbidity and mortality.
Previous studies of AEP interventions showed that participants had improved outcomes on drinking and contraception, and increased knowledge. By participating they may also receive additional educational information and information about support systems available in the local clinic areas, and may elect to reduce drinking or improve contraception use.

Optimizing CARRII for Native women will require measuring the efficacy and costs of components to find a balance between impact and affordability for Native communities. The overarching goal of this R61/R33 proposal is to determine the optimal combination of novel intervention strategies to include with CARRII (tailored for Native women) that maximizes digital intervention efficacy at feasible cost for Native communities.

Continuation

Are you applying for a continuation of your protocol's approval? No

Modification

Does this protocol version include any changes that were made to the previously approved protocol (protocol form, consent documents, etc)? *Minor edits are considered changes!* Yes

Has the level of risk changed (either increased or decreased) since the last submission? No

Provide the rationale for changing the protocol described in this study. Note that the program is able to detect changes made in the text boxes so it is not necessary to report every edit.

Non-Uva Research Team member added.

Unexpected Adverse Events

Did a negative event associated with the research occur and does it meet one of the following conditions:

is not described as a possibility in the previously approved protocol OR;

did not occur within the parameter described (i.e. an increase in frequency or severity)?

Yes

Please describe:

Qualtrics advised the University that on the evening of Monday, Feb. 24, they mistakenly deactivated our HSD Qualtrics portal, resulting in the loss of access to surveys and associated data. Qualtrics completed restoration of the UVA HSD Qualtrics Portal on Tuesday, Mar. 11.

The study coordinator became aware of the disruption in Qualtrics functionality on 2/24/25 as part of regular survey maintenance for Aim 1. She notified Aim 2 participants once the University announced the scope of the issue, without a definitive date for regaining access. Participants were again contacted once this service was restored and tested by study staff.

The CARRII Native intervention used in Aim 2 includes a 7-day diary reflection for participants to complete, and this piece of the Cores is an embedded Qualtrics survey function. Therefore, for 16 days, participants were not able to complete this part of any of the four Cores that they currently had access to.

What was done to negate the incident or minimize risk? If no action was taken, describe why this was the case.

Aim 2 is a 6-week study, so the loss of 16 days of access to Qualtrics also meant that new Cores could not be assigned to participants as scheduled to allow time to complete them all. In order to ensure that participation expectations, interventions, outcomes, and compensation remained fair and equal for all participants, 16 days were added to the original 6-week time period. Participants are being notified of the 16-day extension.

If another service outage such as this occurs, we will notify the IRB through an Unexpected Event and extend the 6-week period again to accommodate the lost time due to the outage.

Please note that one action needed may be to modify the protocol which can be done at this time.

Also, answer "Yes" in the Modification section above and supply the required information.

Is the negative event the result of not following what was described in the protocol? Yes

Please describe:

The loss of 16 days of access to Qualtrics meant that all 4 main Cores of the CARRII Native intervention could not be completed within the original 6-week study time period.