Final Remote Delivery Informed Consent Form

Native-Changing High-risk Alcohol Use and Increasing Contraception Effectiveness Study

NCT03930342

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WASHINGTON STATE UNIVERSITY
Research Study Consent Form
Remote Version

Study Title: Randomized Trial of an Intervention for Preventing Alcohol-Exposed Pregnancy among Women in a Remote Reservation Community

Researchers:

Researcher	Title	Affiliation	Phone Number
Dedra Buchwald, MD	Professor and Director	Washington State University, Elson Floyd College of Medicine, Initiative for Research and Education to Advance Community Health	(206) 708-8665
Karen Little Wounded	Research Coordinator	Missouri Breaks Industries Research Inc., Eagle Butte, SD	(605) 964-1260
Marcia O'Leary, RN	Co-Investigator and Manager	Missouri Breaks Industries Research Inc., Eagle Butte, SD	(605) 964-3418

Sponsor: National Institute on Alcohol Abuse and Alcoholism

You are being asked to take part in a research study. This form tells you about the research study and what will happen if you decide to take part. Ask the study staff or researcher to explain anything you don't understand or repeat any part of this form. You can decide not to join the study. If you join the study, you can change your mind later or quit at any time during the study. If you decide not to take part in the study or quit during the study, you will not incur any penalties or loss of services. This study has been approved by the Washington State University Institutional Review Board, the Great Plains Institutional Review Board, and the Cheyenne River Sioux Tribe.

What is this study about?

This research study is being done to find out if a program called Native-CHOICES can reduce the risk of alcohol-exposed pregnancies among American Indian women. Native-CHOICES encourages women to reduce their alcohol consumption and use birth control methods. Both of these approaches can reduce alcohol-exposed pregnancies.

You are being asked to take part because you are an American Indian woman living on or near the Cheyenne River Sioux Indian reservation and are between the ages of 18 to 44 years old.

We will ask you some questions to determine if you are eligible. You **cannot** take part in this study if you are:

- Under 18 years old
- Pregnant
- Effectively using birth control
- Unable to get pregnant
- Not using alcohol
- Not sexually active with a male partner
- Living with another person who is already taking part in this study.

What will I be asked to do if I am in this study?

If you are eligible, you will be randomly selected to receive either Native-CHOICES or be in a control group. The control group will be offered the same Native-CHOICES program after the main part of the study ends. Regardless of whether you receive Native-CHOICES now or later, you should receive usual health care.

Everyone who takes part in the study will be asked to complete a survey by phone at the beginning of the study and 6 weeks, 3 months, and 6 months after you start the study. The survey takes 60 to 90 minutes. You will be asked about your:

- Use of alcohol and tobacco
- Use of birth control
- Health including feelings and relationships
- Background including age, income, and employment

You do not have to answer any questions that you do not want to answer.

<u>Native-CHOICES Group</u>

Women in this group will be asked to:

- Take part in 2 Native-CHOICES phone or secure videoconference sessions, each of which is about 90 minutes. During the phone/videoconference sessions, you will talk with a Native-CHOICES coordinator to set goals for yourself and work through a study workbook. You will talk about your alcohol use and birth control goals. You should be in a private space during these phone/videoconference sessions. If you cannot be in a private space, the phone/videoconference session will be rescheduled for a time that you can be.
- Talk with a health care provider if you want to discuss birth control options. It is up to you whether or not you talk with a provider. This talk may take up to 30 minutes of your time.
- Decide whether or not to get text or email messages 1 to 2 times a week for 3 months. These texts would be reminders of your appointments or supportive messages about the goals you set for yourself in the sessions.

Control Group

If you are selected to be in the control group, **you will have the option to take part in Native-CHOICES** after your study activities are complete.

How many people will take part in the study?

About 425 people will take part in this study.

Are there any benefits to me if I am in this study?

There may be no direct benefit to you for taking part in the study. Study results may help others in the future.

The study will provide a list of local counseling or other health resources. However, any additional services that you decide to get will be at your own expense.

Are there any risks to me if I am in this study?

You may experience emotional upset when talking about things like your alcohol consumption, feelings, relationships, and use of birth control.

When we call/videoconference you to fill out the screening survey, baseline, 6-week,3-month, and 6-monthsurvey, we will ask you to find a private space where you can answer questions. If you are not able to find a private space, we will find another time to call/videoconference. If you are not in a private space, others may be able to hear your answers to the survey.

If you are in Native-CHOICES, you can choose to get text or email messages about your alcohol use and birth control. If other people see your phone or email, they may be able to see these messages.
If you are in Native-CHOICES, you will also be given workbook materials. Having these materials where you live may also link you to participation in this study.

If you agree to participate remotely you will need to send a text or email documenting your verbal consent. By doing so you acknowledge that email and text are not secure methods of communication and there is a risk that someone could potentially find out about your participation in the study if they have access to your phone or computer.

Study staff must report if you tell us you are going to harm yourself or someone else. Study staff mustalso report if we think there may be any child abuse or neglect or if we think there may be any elderabuse or neglect. If you report a threat to seriously harm yourself or to someone else, or if there is any suspicion of child or elder abuse or neglect, the study staff will be required to report that information to the appropriate authorities.

Study staff are also mandatory reporters following CRST Tribal Ordinance 48. Study staffare obligated to report any participants who are both pregnant and acutely intoxicated atthe time of their visit to local authorities.

The researchers and study staff will do everything possible to protect your information. However, there is a very low chance that study information could be released accidentally. If your study information became known, you could experience negative consequences.

Will my information be kept private?

The data for this study will be kept private to the extent allowed by federal and state law.No published results will identify you by name or in any other way. Under certain circumstances, we may be required to release information that identifies you for internal and external reviews of this project.

Your information, including answers to the survey questions, will be kept separately fromyour name. Procedures are in place to protect your privacy during the study. The surveyyou complete will include a study ID and will not include your name. All surveys will be kept in a locked file cabinet, in a locked office, to which only study staff have access. Anyelectronically stored information will be kept in secure locations. All phone/videoconference sessions will be scheduled at a time when you can be in a privatespace.

Individuals or groups who will have access to study data include all researchers and studystaff, any committees that the review research, funders of the research (the National Institutes of Health), Missouri Breaks Research Institute Inc., and Washington State University.

To help us protect your information, this study has a Certificate of Confidentiality from the National Institutes of Health. This Certificate guarantees that the research team cannot be forced to provide your name or any identifiable research data or specimens in any Federal or state proceedings unless you agree that we can share it. However, we still must report information to local authorities if we learn about child or elder abuse or neglect, or intent to seriously harm yourself or others. We may also need to respond to requests for information from the Department of Health and Human Services or other federal agencies used for audits or program evaluations.

A description of this clinical trial and a summary of the results will be available online at http://www.clinicaltrials.gov, as required by US law. This website will not include information that can identify you. You can search this website at any time.

The results of this study may be published or presented at professional meetings, but the identities of all research participants will remain anonymous.

The data for this study will be kept for at least 6 years after the end of the study.

Are there any costs or payments for being in this study?

There will be no costs to you for taking part in this study.

As shown here, you will receive up to $100 for taking part in this study. You will only receive checks for the activities you finish. If you receive payment, you will be asked to provide your home address.

Study Activity	Check Amount
Baseline interview	$30
6-week interview	$20
3-month interview	$20
6-month interview	$30
Total	**$100**

Optional: After enrollment, if you choose to refer someone else to the Native- CHOICES study and that person successfully enrolls in the study, you may be eligible for an additional $20 check.

The optional components of this study are not essential to your participation in this research. You may choose to participate but if you decline there will be no penalty or loss of services or benefits.

Who can I talk to if I have questions?

If you have questions about this study or the information in this form, please contactthe Research Coordinator, Karen Little Wounded, Missouri Breaks Industries Research Inc., Eagle Butte, SD (605) 964-1260 or at karen.littlewounded@mbiri.com

You can also contact GPIRB Dewey Ertz, EdD at (605) 341-8647 or toll free at (866) 331-5794

You can also contact the researcher – Dr. Dedra Buchwald at Washington State University, Elson S. Floyd College of Medicine, Initiative for Research and Education to Advance Community Health, 1100 Olive Way, Suite 1200, Seattle, WA 98101 or at (20) 708-8622 or at dedra.buchwald@wsu.edu.

If you have questions about your rights as a research participant or would like to report a concern or complaint about this study, please contact the Washington State University Institutional Review Board by phone at (509) 335-7646, or by email at irb@wsu.edu. You may also send sent a letter to Neil 427, PO Box 643143, Pullman, WA 99164-3143.

What are my rights as a research study volunteer?

Your participation in this research study is completely voluntary. You may choose not to be a part of this study or stop taking part at any time. There will be no penalty to you if you choose not to take part. You may choose not to answer any questions that you do not want to answer.

What does my consent to this form mean?

Your consent to this form means that you:

- Understand the information in this form
- Have had all your questions and concerns addressed by study staff or researchers
- Understand the research study and the potential benefits and risks involved

Statement of Consent

I give my voluntary consent to take part in this study.

For Verbal Consent via Phone:

☐ Participant provided verbal consent (Confirmation of Consent will be attached to this form)

_____
Date

_____
Printed Name of Participant

Statement of Person Obtaining Informed Consent

I have carefully explained to the woman taking part in the study what she can expect. I certify that when she signs this form, to the best of my knowledge, she understands the purpose, procedures, potential benefits, and potential risks of participation.

I also certify that she:

- Speaks the language used to explain this research
- Reads well enough to understand this form or, if not, this person is able to hear and understand when the form is read to her
- Does not appear to have any problems that could make it hard to understand what it means to take part in this research.

Signature of Person Obtaining Consent	Date
Printed Name of Person Obtaining Consent	Role in the Research Study