WASHINGTON STATE UNIVERSITY
CONSENT / INFORMATION FORM

Harm Reduction Talking Circles (HaRTC) Study: Phase 3

Washington State University Researchers:

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**We cannot guarantee the confidentiality or security of email communication.

In case of a study-related emergency, please contact 911, your case manager or call the Harborview Emergency Room at 206-744-3074.

RESEARCHERS' STATEMENT

We are asking you to be in a research study conducted by Washington State University, the University of Washington, and Seattle Indian Health Board (SIHB). The purpose of this consent form is to give you the information you will need to decide whether you'd like to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a participant, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

The purpose of this study is to test whether Harm Reduction Treatment Circles, which is a virtual adaptation of Talking Circles, intertribal ceremony where people speak what is on their hearts, are helpful in increasing community connections, reducing alcohol problems, improving quality of life and decreasing use of emergency services. These Harm Reduction Treatment Circles will be provided to people who are current alcohol drinkers, regardless of whether they are ready, willing or able to stop drinking. This approach is called a harm reduction approach. The goal of harm reduction is not to require sobriety but to help people stay safer and healthier, even if they are drinking. For this reason, we call this approach "Harm Reduction Treatment Circles" or HaRTC.

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STUDY PROCEDURES

We will be inviting about 300 people to participate who identify as Indigenous, American Indian or Alaska Native, live in urban areas, and currently drink alcohol. If you choose to be in this study, we will assign you randomly, like flipping a coin, to a group that either receives the HaRTC or does not receive the HaRTC. If you do not receive the HaRTC during your study participation, we will offer you the opportunity to attend HaRTC after your study participation has ended, free of cost. Your participation in this study will not affect the services you receive at any other services agency.

Regardless of your group assignment, you will complete questionnaires and urine tests over a 32-week period. We will make appointments to complete questionnaires with you at the beginning of the study (baseline) and at weeks 4, 8, 12, 20 and 32. Each session will take between 45-60 minutes to complete. You will complete the questionnaires with our study staff via secure telephone/video conferencing (i.e., Zoom).

To be sure we can reach you, we will send you a smartphone (as needed) that has been programmed with Zoom, email, text and telephone capability. During the study, we will pay for unlimited minutes and data to help you participate in the study. We will place some restrictions on how the phone can be used to protect you and your data. While we will not require you to pay for breakage/loss, we will only be able to provide one replacement phone during the study. If you need it, we will loan you this smartphone and provide the data plan so you can safely participate in this study during the COVID-19 pandemic. At the end of your participation, the data plan will end, and we will ask you to return the smartphone to WSU. We will give you a self-addressed, stamped envelope so you can return the smartphone to WSU at no cost to you. It is important the smartphones are returned so they can be used for other important WSU research studies or activities. We expect you to return the smartphones when the study ends, but the cost of returning the smartphones is more than the smartphone is worth. So, WSU will NOT take any legal actions or other actions, like collections processes, against you if you do not send the smartphone back or if it is damaged, lost or stolen.

During the questionnaire appointments, we will ask you questions about your alcohol use and your quality of life. You can skip any of the questions that you do not want to answer, and you are free to stop participating in this project at any time. Here are some examples of the most sensitive questions we will ask you:

- During the past 30 days how often have you felt guilty or ashamed because of your drinking?
- How many days in the past 30 have you used [i.e., crack cocaine, amphetamines/methamphetamines, etc.)?

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At each appointment, we will ask you to produce a urine sample and test it using the urine testing dipcard we will mail you. This will help us look at a marker of alcohol in your urine. You will be asked to show the dipcard results during the assessment.

If you are in the group receiving the HaRTC:

After your baseline appointment, you will be invited to attend 8, Circles provided via video conference. You will be mailed a small smudge kit for your individual use in these Circles, as you prefer. During the Circles, the person who is leading the Circle (Circle Keeper) will introduce themselves and will explain the purpose of the Circle, which is for relatives to have a safe place for sharing from the heart. They will then explain the expectations for the Circle:

- The Circle begins and finishes without interruptions.
- Everyone's voice is valuable.
- While there will not be a physical Talking Piece, the Circle Keeper will let a selected participant know when the virtual Talking Piece has been passed to them. Then, the selected participant will speak until they have finished saying what is on their heart.
- Until a participant is told by the Circle Keeper that the Talking Piece has been passed to them, they will be placed on "mute" so background noises do not distract from what others in the Circle are saying.
- Whatever is shared in the Circle does not leave the Circle. This is a safe space to be open and honest and it is the responsibility of all in the group to maintain the integrity of the circle.

The Circle Keeper will then weave story/knowledge to provide insight into 8 topics related to alcohol use, health, family, community and recovery. Participants will be asked to share their stories and perspectives in response to the topic. The Circle continues in this manner until nothing is left unsaid.

If you are in the group not receiving the HaRTC:

You will attend the video conferenced questionnaire appointments, answer questions, and provide urine test results as outlined above so we can keep track of how you are doing. After your final 32-week follow-up assessment, you will be offered the opportunity to attend a non-study HaRTC if you would like.

AUDIO RECORDING

We will NOT audio record the Circles. We will, however, ask if we can audio record the questionnaire appointments. The recording will be used to make sure we accurately

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record all the information you give us and supervise our staff's work for quality control. We will also write down your answers. You can ask to not be recorded at any time and still participate in the interview. The recording will not have your name or other personal identification on it. Instead you will be given a unique code number. Your code number and name will be kept completely separate from your recording. The recording will be stored on a password-protected, secure server on a password-protected, encrypted computer. The recording will be destroyed after the completion of the study.

RISKS, STRESS, OR DISCOMFORT

Risks associated with participation are primarily related to the sensitivity of some of the questions we may ask you. For example, you will be asked about thoughts, feelings, experiences, and personal difficulties that may be private, including questions about your alcohol use. These questions may make you feel uncomfortable, seem private, bring up bad memories, or you may become concerned about your alcohol use as you answer the questions. If you become concerned about your alcohol use or experience discomfort as a result of your participation in this particular study, you can contact one of the investigators listed above to discuss this. If you are in crisis, you can contact the National Suicide Prevention hotline at 1-800-273-8255. Our team can also suggest local medical and mental health resources, including Urban Indian Health Organizations (https://www.ncuih.org/UIHOs_locations).

BENEFITS OF THE STUDY

There may be no direct benefit to you for participating in this research. However, you may benefit by learning more about yourself through answering some of the questions. If you are in the group receiving HaRTC, you may benefit by feeling more connected to your community and feeling better through discussions about your hopes for the future and safer drinking strategies. Your participation may also help providers better help people in the future.

SOURCE OF FUNDING

The WSU and UW research teams are receiving financial support from the National Institutes of Health for this research study. We have a Memorandum of Understanding with SIHB to complete this research project collaboratively.

CONFIDENTIALITY OF RESEARCH INFORMATION

Your participation in the interview is confidential. That means everything you tell us will be kept private.

- Your name will not be on the interview.
- The information you provide us will not be linked to your name. It will be marked with a study ID instead. Your data will therefore be collected without identifiers.

- We will keep the audio recording from the interview on password-protected, encrypted computers. The audio recording will be destroyed after the end of the study.
- Your name will not be used in any reports or publications from this study.

However, if we learn that you intend to harm yourself or others, or about a child or elder who is being abused, we must report that to the authorities.

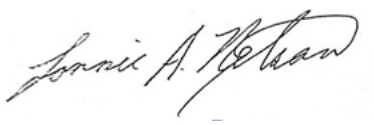
OTHER INFORMATION

This study has been approved for human subject participation by the Washington State University Institutional Review Board. It has also been reviewed and approved by the SIHB/UIHI Research Advisory Board. This study has a certificate of confidentiality from the National Institutes of Health (NIH). A description of this clinical trial is available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

It is your choice to be in the study. Nothing bad will happen to you if you choose not to participate. The services you receive from SIHB or any other provider will not be affected in any way by your decision to participate or not participate in the study. You can stop the interview at any time. You can also drop out of the study at any time and that will not affect your current or future services.

You will receive a $40 thank you giftcard for completing each interview with the research team. You will also all study materials needed (e.g., urine test dipcards, mobile telephone). As noted above, you will be able to keep the mobile telephone you receive after the study ends.

If you have any questions, we can answer them now. You can also contact the people listed at the beginning of this form or our study phone line (phone number) or email (email address).

Lonnie A. Nelson, PhD		9/10/20
Contact PI	Signature	Date

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PARTICIPANT'S STATEMENT

√ This study has been explained to me.
√ I volunteer to take part in this research.
√ I have had a chance to ask questions.
√ If I have questions later about the research, I can ask one of the researchers listed above.
√ 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 at (509) 335-3668, or e-mail irb@wsu.edu, or regular mail at: Neill 427, PO Box 643143, Pullman, WA 99164-3143.
√ I will receive a copy of this consent form.

___ Yes ___ No	Please mark whether or not you would like to participate in the audio recorded session.

___ Yes ___ No	Please mark whether or not you agree to participate in this study. This is called "verbal informed consent."

Printed name of participant Signature of participant Date

Copies to: Researcher, Participant

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