

Southwest Hub for American Indian Youth Suicide Prevention Research

NCT03543865

Consent

3 February 2023

JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH

ADULT INFORMED CONSENT DOCUMENT

Study Title: Southwest Hub for American Indian Youth Suicide Prevention Research

Principal Investigator: Mary Cwik, PhD

IRB No.: 00008138

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What you should know about this study

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- You are a volunteer. You may choose not to take part at all, and if you join, you may quit at any time. There will be no penalty if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.

Purpose of research project

This research is being done to measure the effectiveness of two brief programs to reduce suicidal thoughts or substance use and increase resilience among Native Americans ages 10-29, in addition to regular follow-up visits. Some youth will have the option to participate in a data collection sub-study on opioids.

We will make sure you understand all the study procedures. You should ask questions at any time. You must sign this form in order to join the study. We will give you a copy of this form for your records.

Why we are asking you to participate

You are being asked to join this study because you are Native American age 10 to 29 years old and you have recently had suicidal thoughts, engaged in binge drinking and/or drug use, or attempted suicide, or returned from in-patient care related to suicide thoughts or attempt as identified by Celebrating Life surveillance system. A Celebrating Life Case Manager from the community will ask you questions to confirm you are eligible for the study. We expect a total of 304 youth and young adults to participate in the main study, up to 30 of whom will also participate in the sub- study.

Study procedures

If you join this study, we will ask you to allow a trained Celebrating Life Case Manager to visit you at your home or another private location at least five times over a six-month period. You will have one visit in the next few days, and then monthly visits for the next 3 months. Your last visit will happen six months from now. The sub-study consists of one additional visit.

During these visits, the Celebrating Life Case Manager will ask you to complete a series of questions on a tablet device about how you are thinking, feeling and behaving. Some of these questions will deal with your knowledge, attitudes, beliefs and experiences related to opioid use. If you are not already in

contact with local services and resources, the case manager will also help you get connected to these services in the community. We will also access your medical records, including the type of diagnoses, treatments, amounts billed and paid, for the past two years and during the time you participate in the study to help understand how often you have received medical care and what are the costs associated with the healthcare received during these time periods.

In addition to case management, you may be expected to participate in one or two additional program visits which will take 2-4 hours each. The decision about which brief program you are offered will be made randomly, like flipping a coin. You may be chosen for one, both or to continue with case management services usually offered in the community. If you are invited to participate in program visits, they will be audio-recorded and transcribed for quality assurance purposes. Recordings will be kept confidential and destroyed once quality assurance forms are completed. Transcripts will be de-identified, stored in a secure, online database and deleted at the end of the study.

Possible Additional Program Visits Include:

1. **New Hope (within next month):** A Celebrating Life Program Educator will teach you (and a support person, optional) in your family coping skills, the importance of social support, and how to keep yourself safe from suicide and drinking or using drugs too much.
2. **Elders' Resiliency (between 2 to 3 months from now):** A Celebrating Life Program Educator and Elder will teach you about cultural identity, values and language, in addition to your importance and role in your community.

Opioid Data Collection Sub-Study:

Up to 30 participants will be asked to participate in one additional 60-90 minute individual interview if they report knowledge or experience with opioids in your community. When we use the term opioid use, we mean any use of heroin, methadone or suboxone, as well as prescription pain medicines such as oxycontin, percocet, vicodin, morphine, dilaudid, and fentanyl without a prescription from a doctor.

1. **Interview about Opioids:** A Celebrating Life Case Manager may approach you to participate in one additional 60-90-minute visit which will be a one-on-one interview about your personal knowledge, experience and attitudes about opioid use in the community. Interviews will be audio-recorded and transcribed for analysis. Recordings will be kept confidential and destroyed once transcription is completed. Transcripts will be de-identified, stored in a secure, online database and deleted at the end of the study.

We won't report anything you tell us in the questionnaires, what we learn about from the medical records, or during visits unless we're worried you might hurt yourself, you might hurt someone else, someone is hurting you, or you have a high-risk score on a validated clinical tool (Opioid Risk Tool). The Opioid Risk Tool is a brief, self-report screening tool designed to assess risk for opioid abuse. Individuals categorized as high-risk are at increased likelihood of future abuse drug related behavior. Celebrating Life Case Managers will make sure you understand all the study procedures. You should ask questions at any time. You must sign this form to be able to join the study.

Safety Questionnaires

At the end of each visit, we want to make sure that you are not in danger of hurting yourself. Your Celebrating Life Case Manager will give you a questionnaire that asks about suicidal thoughts and

behaviors you might be having. Based on your responses to the questions, we may do the following:

- If you seem to be at some risk for hurting yourself, we will call the senior staff person on site to review your case and develop a plan to help you. The head of the program and senior program team members will also be notified and will assist with developing the plan.
- If you seem to be at medium to high risk for hurting yourself, we will tell the on-site senior program staff person right away. We will either set up an appointment for you right away with the Celebrating Life Team, or we will set up an appointment for you right away with Apache Behavioral Health Services.
- If you seem to be at very high risk for hurting yourself, we will immediately contact the tribal police, then the on-site senior staff member. We need to call the police so that they can pick you up and drive you to the Emergency Department at the Whiteriver Service Unit for an emergency evaluation or a Celebrating Life team member will escort you to the Emergency Department at the Whiteriver Service Unit.
- If current opioid use is identified, substance specific referrals and case management will be given. Second, you will complete the Opioid Risk Tool *at the study visit* with one of two study staff with. This screener will allow the study team to determine if you can continue in the trial, in addition to get them into the most appropriate treatment. In cases where participants score in the high-risk category, the local research staff will consult with the two Co-PIs. The main factor for deciding whether they can continue in the trial is whether participating in our study is interfering with them participating in needed opioid treatment (i.e., participation in our trial may be a barrier to the time commitment needed for substance use treatment) or vice versa— i.e., participation substance abuse treatment may be a barrier to the time commitment needed to participate in our trial.
- In addition, if we find out that you are not currently at risk for hurting yourself but did try to hurt yourself at another time while in this program, we will contact the Celebrating Life Team so they can follow-up with you. We will also talk to the Celebrating Life Team about whether it is a good idea for you to stay in this program.

Risks/discomforts

The main burden to you is the amount of time it will take to complete the study visits. Each of the five case management and assessment visits will last about an hour or two. This would equal 6 total hours of your time over 6 months. If you are also selected to receive the program visits, this would add 4-8 hours (for a total of 10-14 hours over 6 months' time). You may be uncomfortable completing the questionnaires. Some people may be uncomfortable talking about or reporting about their mental health and risky behaviors.

We hope you will feel more comfortable knowing our study staff are trained to discuss sensitive topics appropriately, be good listeners, keep your information private and confidential, and connect you to appropriate resources in the community.

Benefits

All participants will likely benefit from case management visits and that help facilitate access to additional services you may need. If you receive one or both of the brief programs, it is possible that you may have less suicidal thoughts or binge drinking, and stronger coping skills and resilience. Your participation will also benefit your community and science by helping to understand if either of these two programs help young Native Americans.

Payment

You will receive a gift card for participating in each of the five evaluation visits and once you complete the assessments:

Assessment 1	\$20
Assessment 2	\$25
Assessment 3	\$30
Assessment 4	\$35
Assessment 5	\$40

Participants who complete all five case management and assessment visits can receive a maximum of \$150 over the course of 6 months. You will receive payments only for the assessments you completed. You will not receive compensation for participating in program visits. Participants in the Opioid Data Collection Sub-Study will receive an additional \$25. The Celebrating Life staff will not be responsible for lost or stolen gift cards and you will not receive another gift card should it be lost or stolen.

Data Confidentiality and Data Sharing

To keep your information private, we will assign you a code number when you start the study. Any information we collect from you will only have this code number on it. We will keep a separate list that links your study code number to your name. This list will be private and all information about you will be stored in a locked file cabinet in the Johns Hopkins field office. All electronic data will be stored on computers that are password protected. If in the future your tribe allows the study data to be accessed by the general public, there will be no way to link the data to your personal information.

You cannot be in the study unless you agree that we can use the information you provide to evaluate the study findings. No identifying information will be included with the data that is analyzed. There will be no way to identify you in any publications or study results.

Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means. It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help. Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

There are a few times when we will not be able to keep your information private. We may be required to give out information about you if the government audits us. The research team will also give information to the appropriate local or state authorities:

- if you appear to be at risk for hurting yourself including from opioid use;
- if they suspect abuse or neglect of a child or dependent adult;
- if the team learns that you plan to harm someone else. In this case, the team also may warn the person who is at risk.

Protecting your privacy during data collection

The case management and assessment visits will be conducted in a private location of your choosing. Program visits will be done in private locations determined by you with the Celebrating Life Program Educators and/or Elders. If any of these individuals, including you, feel as though the location is not suitable, the questionnaires and/or programs may be stopped and moved to a more private location.

Your alternatives to joining the study

You do not have to join and participate in this study. The alternative is not to participate in the study. As needed or requested, Celebrating Life Case Managers will refer all individuals to care outside of the study, including referrals to mental health care providers, traditional healers, and spiritual leaders.

Cost of participation in the study

There are no anticipated costs to participate in this study.

What happens if you leave the study early?

You may leave the study at any time without any penalty, including only stopping the program but continuing with the assessments and case management. Please note, if you decide to withdraw from the study at any time, it will not affect the care you receive at WRSU/IHS. Participants who stop all parts of the study early are able to continue case management through the Celebrating Life Surveillance system. If we feel that it is not in your best interest to continue with the study, if you move off-reservation, or are relocated for treatment, you will not be expected to participate in the rest of the study.

Ending Consent

You may end your consent at any time. Information obtained and used before you end your consent will continue to be used for research. If you do not want your information continued to be used for research, please let us know. If you wish to end your consent, let us know.

Who do I call if I have questions or problems?

- Call the principal investigator, Dr. Mary Cwik, at 410-955-6931 if you have questions or complaints or get sick or injured as a result of being in this study.
- Call or contact the **Johns Hopkins Bloomberg School of Public Health IRB Office** if you have questions about your rights as a parent of a study participant. Contact the IRB if you feel you have not been treated fairly or if you have other concerns.
 - The Johns Hopkins IRB contact information is:
Address: Johns Hopkins Bloomberg School of Public Health
615 N. Wolfe Street, Suite E1100
Baltimore, MD 21205
Telephone: 410-955-3193
Toll Free: 1-888-262-3242
E-mail: jhsph.irboffice@jhu.edu
- **Whiteriver Mountain Apache:** Derek Patton, Phoenix Area IHS IRB at (480) 228-8981.

What does your signature on this consent form mean?

Your signature on this form means:

- You have been informed about this study's purpose, procedures, possible benefits and risks.
- You understand that if you are asked to participate in them, program visits and opioid interviews will be audio-recorded.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to be in this study.

Print name of Adult Participant

Signature of Adult Participant

Date

Print name of Person Obtaining
Consent

Signature of Person Obtaining Consent

Date