

**Southwest Hub for American Indian Youth Suicide Prevention Research**

**NCT03543865**

**Consent**

**3 February 2023**

**JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH**  
**RESEARCH ASSENT FORM**

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

**Principal Investigator: Mary Cwik, PhD**

**IRB No.: 00008138**

**PI Version Date: Version 5, February 3, 2023**

**Purpose of the study**

We want to tell you about a research study we are doing. Research allows us to collect information from people to help us answer questions about health. We would like to find out more about how to best help Native American youth from hurting themselves. Some youth will have the option to participate in a data collection sub-study on opioids.

**Why you are being asked to join the study**

You are being asked to join the study because you have recently had thoughts of suicide, attempted suicide, or engaged in binge drinking, or recently returned from in-patient care related to suicide thoughts or attempt. We hope to include about 304 other youth and adolescents like you in the main study, up to 30 of whom will also participate in the sub-study.

**Procedures**

If you agree to join this study, you will be asked to allow a 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 complete an initial assessment, and then monthly visits for 3 more months. The last visit will happen about six months from now. The sub-study consists of one additional visit.

The Celebrating Life Case Manager will ask you to answer a series of questions on a tablet each time they visit you. 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 to help understand how often you are getting medical care.

In addition, a Celebrating Life Program Educator may visit one or two extra times, which will last 2-4 hours each (also at your home or another private location). The decision about which brief programs you are offered to participate in will be made randomly, like flipping a coin. You may be chosen for one, both or to continue with case management services as usually offered in the community.

**Possible Additional Program Visits Include:**

1. **New Hope (within next month):** A Celebrating Life Program Educator will teach you (and an adult in your family) ways to help you stay safe when you feel like hurting yourself or drink too much.
2. **Elders' Resiliency (between 2 to 3 months from now):** A Celebrating Life Program Educator and Elder will teach you about the Apache culture, identity values and language.

### **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.

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 do not appear to be at risk for hurting yourself, your answers will be reviewed by an experienced member of our staff within two days to be sure that there is limited risk.
- 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, a two-fold strategy will be given. First, substance specific referrals and case management will be implemented. Second, you will complete the Opioid Risk Tool *at the study visit* with one of two study staff with masters in professional counseling. 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 have a high score, the local research staff will consult with the two Co-PIs. The main factor for deciding whether they can continue in the study is whether participating in our study is interfering with them participating in needed treatment for their opioid use.
- 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.
- Your parent(s) will be notified and involved in the above steps if you are determined to be at high risk.

## **Risks**

The assessment visits will take about an hour or two each. If you receive the additional program visits, study participation may take up to 14 hours over the next 6 months.

Some of the questions we will ask as part of the evaluation may make you uncomfortable. We will ask about your thoughts about hurting yourself. You may skip any questions you want or take time thinking about your responses. We will keep your answers private and will not share them with your parent/guardian. However, there will be an *exception* to our promise to keep your opioid use responses private. If your score from the opioid risk tool shows that your risk of harm is high, we will notify your parents.

We hope you will feel more comfortable knowing that our study staff are trained to be good listeners and are there to help you.

## **Benefits**

You might learn better ways to deal with your thoughts and stop hurting yourself or stop opioid use. You also might learn more about your Apache culture, identity, values and language. We also hope to learn something that will help other Apache youth and adolescents who struggle with these issues.

## **Payment**

You will receive gift cards upon completion of each of the five assessment visits with your Celebrating Life Case Manager for answering the questions they ask you. The amount will increase with each visit:

<b>Assessment 1</b>	\$20
<b>Assessment 2</b>	\$25
<b>Assessment 3</b>	\$30
<b>Assessment 4</b>	\$35
<b>Assessment 5</b>	\$40

If you complete all five assessments, you can get up to \$150. If you do not complete an assessment, you will not receive a gift card for that visit. To keep things fair, nobody will receive gift cards for the additional brief program visits (New Hope and Elders' Resiliency). 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.

## **Voluntary participation**

You do not have to join this study. It is up to you. You can say okay now, and you can change your mind later. All you have to do is tell us. No one will be mad at you if you change your mind.

## **Do you have any questions?**

**If you want to be in this study, please sign your name. You will get a copy of this form to keep for yourself.**

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(Sign your name here)

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(Date)

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(Signature of Person Obtaining Assent)

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(Date)