

Southwest Hub for American Indian Youth Suicide Prevention Research

NCT03543865

Consent

3 February 2023

**JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH
PARENTAL PERMISSION 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 permit your youth to join a research study.
- This consent form explains the research study and your youth's part in the study.
- Please read it carefully and take as much time as you need.
- Your decision to let your youth participate must be voluntary. You may choose not to let your youth take part at all, and if you let your youth join, you may decide to quit at any time. There will be no penalty if you decide to end your youth's participation in the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to let your youth 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 and your youth understand all the study procedures. You should ask questions at any time. You must sign this form in order for your youth to join the study. We will give you a copy of this form for your records.

Why we are asking your youth to participate

Your youth is being asked to join this study because they are Native American age 10 to 29 years old and have recently had suicidal thoughts, engaged in binge drinking and/or drug use, or attempted suicide, or recently returned from in-patient care related to suicidal thoughts or attempt as identified by Celebrating Life surveillance system. A Celebrating Life Case Manager will ask your youth questions to confirm they 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 your youth joins this study, we will ask you and your youth to allow a trained Celebrating Life Case Manager to visit you and your youth at your home or another private location. These visits will occur at least five times over a six-month period. Your youth will complete an initial assessment, and then have monthly visits for the next 3 months. Your youth's last visit will happen about six months from now. The sub-study consists of one additional visit.

During these visits, the Celebrating Life Case Manager will ask your youth to answer a series of questions on a tablet device about how they are thinking, feeling and behaving. Some of these questions will deal with your youth's knowledge, attitudes, beliefs and experiences related to opioid use. *If* your youth is not already in contact with local services and resources, the case-manager will also help them get connected to these services in the community. We will also access your youth's medical billing records, including the type of diagnoses, treatments, amounts billed and paid, for the past two years and during the time your youth participates in the study to help understand how often they have received medical care and what are the costs associated with the healthcare received during these time periods.

In addition to case management, your youth may be expected to participate in one or two additional program visits which will take 2-4 hours each. The decision about which brief programs your youth is offered to participate in will be made randomly, like by flipping a coin. Your youth may be chosen for one, both or to continue with services as 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 Intervention Visits Include:

- 1. New Hope (within next month):** A Celebrating Life Program Educator will teach your youth and an adult in your family coping skills, the importance of social support, and how to keep themselves safe from suicide and drinking too much.
- 2. Elders' Resiliency (between 2 to 3 months from now):** A Celebrating Life Program Educator and Elder will teach your youth about cultural identity, values and language, in addition to their importance and role in their 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 your youth tells us in the questionnaires, what we learn about from the medical records, or during visits unless we're worried your youth might hurt themselves, they might hurt someone else, or someone is hurting them, or if they 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 your youth understands all the study

procedures. Your youth can ask questions at any time. You must sign this form for your youth to be able to join the study.

Safety Questionnaires

At the end of each visit, we want to make sure that your youth is not in danger of hurting himself/herself. Your Celebrating Life Case Manager will give your youth a questionnaire that asks about his/her suicidal thoughts and behaviors he/she might be having. Based on the responses to the questions, we may do the following:

- If your youth seems to be at some risk for hurting himself/herself, we will call the senior staff person on site to review your case and develop a plan to help him/her. The head of the program and senior program team members will also be notified and will assist with developing the plan.
- If your youth seems to be at medium to high risk for hurting himself/herself, we will tell the on-site senior program staff person right away. We will either set up an appointment for him/her right away with the Celebrating Life Team, or we will set up an appointment for him/her right away with Apache Behavioral Health Services.
- If your youth seems to be at very high risk for hurting himself/herself, 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 your youth up and drive him/her to the Emergency Department at the Whiteriver Service Unit for an emergency evaluation or a Celebrating Life team member will escort him/her to the Emergency Department at the Whiteriver Service Unit.
- If current opioid use is identified with your youth, a two-fold strategy will be given. First, substance specific referrals and case management will be implemented. Second, your youth 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 your youth 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 your youth is not currently at risk for hurting himself/herself but did try to hurt himself/herself 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.
- You will be notified and involved in the above steps if your youth is determined to be at high risk.

Risks/discomforts

The main burden to your youth is the amount of time it will take to complete the assessments. 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). Your youth may be uncomfortable completing the questionnaires. Some people may be uncomfortable talking about or reporting about

their mental health and risky behaviors.

We hope your youth will feel more comfortable knowing our study staff are trained to discuss sensitive topics appropriately, be good listeners, emphasize the importance of confidentiality, keep your youth's information private and connect them to appropriate resources in the community. Please note, that we will not notify or disclose anything to you that your youth discloses to us during this study. The only time we will notify you is if your youth's score from the opioid risk tool shows that their risk of harm is high.

Benefits

All participants will likely benefit from case-management visits and help with facilitating access to additional services if needed. If your youth receives one or both of the brief programs, it is possible that your youth may have less suicidal thoughts or binge drinking, and stronger coping skills and resilience. Your youth's participation will also benefit your community and science by helping to understand if either of these two programs can help Native American youth.

Payment

Your youth will receive a gift card for participating in each of the five assessment visits and completing the questionnaires:

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. Your youth will receive payments only for the visits they completed. Your youth 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 your youth will not receive another gift card should it be lost or stolen.

Data Confidentiality and Data Sharing

To keep your youth's information private, we will assign them a code number when they start the study. Any information we collect from them will only have this code number on it. We will keep a separate list that links your youth's study code number to their name. This list will be private and all information about your youth 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 youth's personal information.

Your youth cannot be in the study unless you agree that we can use the information they 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 youth's information even if requested using legal means. It does not protect information that we have to report by law, such as youth abuse or some infectious diseases. The Certificate does not prevent us from disclosing your youth's information if we learn of possible harm to themselves or others, or if they 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 youth's information private. We may be required to give out information about your youth if the government audits us. The research team will also give information to the appropriate local or state authorities:

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

Protecting your youth's privacy during data collection

The case management and assessment visits will be conducted in a private location of you or your youth's choosing. Intervention visits will be done in private locations determined by the Celebrating Life Program Educators and/or Elders. If any of these individuals, including you or your youth, 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 permitting your youth to join the study

You do not have to allow your youth 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 your youth leaves the study early?

Your youth may leave the study at any time without any penalty. Please note, if your youth decides to withdrawal from the study at any time, it will not affect their care they receive at WRSU/IHS. Your youth may stop the program but continue with the assessments and case management. 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 youth's best interest to continue with the study, if you or your youth move off-reservation, or are relocated for treatment, your youth will not be expected to participate in the rest of the study.

Ending Consent

You may end your permission at any time. Information obtained and used before you end your permission will continue to be used for research. If you do not want your youth's information continued to be used

for research, please let us know. If you wish to end your permission allowing your youth to participate, 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
- **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 allow your youth to be in this study.

Print name of Parent/Legal Guardian

Signature of Parent/Legal Guardian

Print name of Youth

Print name of Person Obtaining
Consent

Signature of Person Obtaining Consent